

The Breast and Cervical Screening Manual

A Guide for Health Departments
and Providers

Revised August 2006

Collaboration Partners:

Chronic Disease and Injury Section,
Breast and Cervical Cancer Control Program
Comprehensive Cancer Program
Medical Advisory Committee for the Breast and Cervical Cancer Control Program
Women's and Children's Health Section

North Carolina Department of Health and Human Services Division of Public Health



State of North Carolina
Department of Health and Human Services
Division of Public Health • N.C. Breast and Cervical Cancer Control Program
www.ncdhhs.gov



North Carolina Department of Health and Human Services
Division of Public Health • Chronic Disease and Injury Section
Cancer Prevention and Control Branch
Breast and Cervical Cancer Control Program

1922 Mail Service Center • Raleigh, North Carolina 27699-1922
Tel 919-707-5300 • Fax 919-870-4812

Michael F. Easley, Governor
Carmen Hooker Odom, Secretary

Leah Devlin, DDS, MPH, Director

July 11, 2006

MEMORANDUM

To: Local Health Directors
Nursing Directors/Supervisors

From: Leah Devlin, DDS, MPH, State Health Director
Marcus Plescia, MD, MPH, Chronic Disease and Injury Section

Subject: Revised Breast Screening Manual: A Guide for Health Departments and Providers,
(July 5, 2006)

Date: July 5, 2006

Enclosed is the revision of the Breast Screening Manual, replacing "Breast Health: A Guide for Health Departments" published in 1994. The revision is an interdepartmental collaboration between the Division of Public Health - Chronic Disease and Injury Section, North Carolina Breast and Cervical Cancer Control Program, Comprehensive Cancer Program, and Woman's and Children's Health Section.

The current guidance from Center for Disease Control and Prevention, National Cancer Institute, American Cancer Society, U.S. Preventive Services Task Force, College of Obstetricians and Gynecologists, and the American College of Radiology is encompassed in the Breast Screening Manual.

The Division of Public Health document is to be used as a model and template for writing policies and procedures to recruit, screen, diagnose, and treat women with breast cancer. In keeping with our mission, to work in partnership with local communities to improve the quality life and save the lives of women in North Carolina this manual will be helpful in delivery of health care services to the public. We thank you and appreciate the work you do to improve the quality of life for North Carolina women.

ACKNOWLEDGEMENTS

Breast and Cervical Screening Manual: A Guide for Health Departments and Providers Revised August 2006

This Breast Manual was reviewed and revised through the collaborative efforts of representatives of the following Division of Public Health sections and programs:

Chronic Disease and Injury Section
Breast and Cervical Cancer Program
Comprehensive Cancer Program
Women's and Children's Health Section

The Breast Manual Committee expresses gratitude and appreciation to all individuals who worked toward the successful completion of the Breast Screening Manual.

Breast Manual Committee

Betty Cox, RN, MSHA, Chairman
Gerald G. Britt, BA
Vicki Deem, RN, MPA
Amy Denham, M.D.
Connie Kelley-Sidberry, RN, MPH
Etta D. Pisano, MD, FACR
Leah Thorndyke, BSN

The Breast Manual Reviewers

Pat Canon, RN, MPA
Linda J. Carter, BSPH, M.Ed
Ida J. Dawson, MHS, PA
Taryn Edwards, RN, BSN
Joe Holliday, MD
Freda Johnson, RN, BSN
David W. Olilla, MD
Marcus Plescia, MD
Carolyn Sartor, MD
Walter Shepherd, MA

Breast and Cervical Cancer Program Staff Comprehensive Cancer Program Staff

Katherine Denton, MS
Janet Dail

Breast and Cervical Screening Manual

A Guide for Health Departments and Providers

Table of Contents

TABLE OF CONTENTS	i
OVERVIEW	ii
I. Breast Cancer Screening and Breast Cancer Risk Factors	
Breast Cancer Risk Factors	I-1
Breast Cancer Screening Components	I-3
NC BCCCP Guidance on Screening Mammography	I-7
Mammography Age Guidance – Government and Professional	I-8
Breast Self-examination Instruction Sheet (English)	I-10
Breast Self-examination Instruction Sheet (Spanish)	I-11
Clinical Breast Exam Procedure	I-12
Examination of Lymph Nodes	I-15
II. Quality Assurance	
QA Recommendations for Breast Cancer Screening	II-1
Patient Notification Requirements	II-3
III. Management of Abnormal Clinical Findings	
Abnormal Clinical Findings	III-1
Algorithm for Management of Findings on Breast Screening	III-5
Algorithm on Managing Palpable Masses	III-6
Algorithm on Managing Fibroadenoma	III-7
IV. Interpretation of Mammography Reports	
Organization of the Mammography Report	IV-1
American College of Radiology Breast Imaging and Reporting Data System BI-RADS® Atlas	IV-2
V. Appendices	
A. Glossary	A-1
B. N. C. BCCCP Eligibility and Other Funding Resources	B-1
BCCCP Program Description	B-3
Breast and Cervical Cancer Medical	B-4
C. Non-BCCCP Funding Sources	
Cancer Assistance Unit Funding	C-1
Resources Outside of N.C. BCCCP	C-3
D. Dose to Staff who Restrain Patients During Mammography	D-1

Breast and Cervical Screening Manual

A Guide for Health Departments and Providers

Table of Contents (continued)

E.	Breast Cancer Staging	E-1
	Reprint from "CA: A Cancer Journal for Clinicians"	E-2
F.	NBCCEDP Breast Cancer Expert Panel - White Paper	F-1
G.	Resources	
	NC BCCCP Staff Directory	G-1
	Breast Cancer Links	G-2
	Patient Advocate Foundation	G-4
VI.	Bibliography	VI-1



North Carolina Department of Health and Human Services

Division of Public Health • Chronic Disease and Injury Section

Cancer Prevention and Control Branch

Breast and Cervical Cancer Control Program

1922 Mail Service Center • Raleigh, North Carolina 27699-1922

Tel 919-707-5300 • Fax 919-870-4812

Michael F. Easley, Governor

Carmen Hooker Odom, Secretary

BREAST HEALTH

The National Cancer Institute, using current rates, estimates that women living the United States have a 13.2%, or a 1 in 8, lifetime risk of being diagnosed with breast cancer. Estimated risk is an average risk for all women. Individual risk factors include age, family history, reproductive history, race and ethnicity, as well as other factors.

Women in North Carolina have the same lifetime risk as the national average. In their annual projections, the American Cancer Society (ACS) that 6,290 women would be diagnosed with breast cancer in 2006, and an estimated 1,210 women would die of breast cancer in North Carolina. Breast cancer is the second leading cause of cancer deaths in North Carolina women. The burden of breast cancer falls heavily on low-income and minority women, particularly women in rural North Carolina.

Nationally, the disparity in five-year survival rates between white women (90%) and African-American women (76%) still exists, according to the American Cancer Society. Lower survival rates in African-American women are attributed to later stage detection of their breast cancers and the higher rate of more aggressive breast cancers in young African-American women.

Early detection and treatment of breast cancer is saving lives. In August 2005, the American Cancer Society reported breast cancer mortality has declined 2.3 percent since 1990. With improvements in early detection and treatment, more cases of breast cancer will be diagnosed and treated at earlier stages, and breast cancer mortality will continue to decrease.

Risk Factors And Recommendations That Impact Breast Cancer

Scientists and physicians cannot explain why one woman gets breast cancer and another does not. Scientists have studied patterns and have found that what goes on around us and in our personal habits can increase our chances of developing cancer. According to the National Cancer Institute, “prevention means avoiding the risk factors and increasing the protective factors that can be controlled so that the chance of developing cancer decreases.” While risk factors can be avoided, avoidance does not necessarily guarantee a life free of breast cancer.

The National Cancer Institute Findings:

- Populations that eat a high-fat diet are more likely to die of breast cancer.
- Certain vitamins may decrease a woman’s risk of breast cancer, especially for premenopausal women at high risk.
- Exercise, especially in young women, may decrease hormonal levels and decrease breast cancer risk.
- Breast feeding reduces breast cancer risk.
- Alcohol consumption may be associated with a slightly increased risk of breast cancer.
- Postmenopausal weight gain after natural menopause and/or after age 60 may increase breast cancer risk.

The American Cancer Society Findings:

- Some Risk Factors That Are Not Easily Changed:
 - Family history of breast cancer
 - Having first period before twelve
 - Not having children or not having first child until after age 30
 - Late age at menopause
- Some Risk Factors That Are Easily Changed:
 - Limiting the use of hormones (hormone replacement therapy)
 - Reducing alcohol consumption
 - Breast feeding
 - Avoiding obesity
 - Being physically active

There is no consensus on the effects of smoking or the consumption of soy products on breast cancer. Additionally, there is no consensus that a high-fat diet or a low-fat diet affects a woman’s risk of breast cancer beyond the health benefits associated with low-fat diets (lowering blood pressure, reducing strokes, and heart disease).

The Best Preventive Recommendations for Breast Cancer:

- Achieve and maintain a healthy weight
- Be physically active
- Consume a minimum of five servings of a variety of fruits and vegetables per day
- Consume alcoholic beverages in moderation (or not at all)
- Enjoy the health benefits of a low-fat diet

Screening for Breast Cancer in North Carolina

A. Three components of breast cancer screening:

1. Breast Self Examination
2. Clinical Breast Examination
3. Age-appropriate mammogram

B. Patient Education: Written materials should be provided to the patient on Self Breast Examination (BSE), Clinical Breast Examination (CBE) and mammography to reinforce staff recommendations. Materials should include:

1. Techniques and normal findings (see page I-10)
2. Indications for calling provider about signs or symptoms of breast cancer
3. Importance of age-appropriate screening
4. Explanation of procedures: CBE, mammogram
5. Limitations of screening:
 - Normal results on a screening examination do not necessarily indicate absence of disease.
 - Normal results never rule out the later development of disease, which is why ongoing regular screening is so strongly recommended.
 - No screening test is 100% accurate; therefore, some cases of the disease may be unavoidably missed.
 - Breast abnormalities fall into two categories: (1) benign and (2) malignant. About 6 - 20% of women with abnormal screening are diagnosed with breast cancer.
6. Reinforce the importance of following through with screening and follow-up. Some women experience anxiety about screening that creates barriers to care. Some of these include cultural values, loss of time from job or family, cost if they are inadequately insured, lack of confidence in the procedures, fear of or actual pain during the procedures, perceived dangers of radiation, blaming themselves if something is abnormal and ultimately “hearing the worst.”

C. Clinical Breast Exam: A CBE is the physical examination of the breast that is performed by a health care provider (family physician, gynecologist, registered nurses, physician's assistant, and nurse practitioner). A CBE should be performed at least every three years beginning at age 20 and every year beginning at age 40. A CBE may be recommended more often if the patient has a family history of breast disease. Clinical Breast Examinations are best performed soon after the end of a patient's menstrual period. The breasts are not as tender or swollen as during the menstrual period. Unusual changes are easier to detect at the end of the menstrual cycle.

The examination should be conducted in a setting that allows for minimal distractions and adequate patient privacy. Examination gowns should be adjusted to minimize unnecessary exposure of the patient. The examinations should be conducted unhurriedly. A complete clinical examination should take from 5 to 10 minutes. Nurses should not administer a breast exam unless they have completed the Adult Physical Assessment course through the Office of Public Health Nursing or a compatible course for which they are certified. The clinical breast exam should be performed using the vertical strip method. A more detailed guide may be found on page I-12. Components of the breast examination are:

1. Breast health history:

- Description of present breast symptoms, using History of Present Illness Components
- Lumps, pain, nipple discharge, changes in shape, difference between breasts, cyclic tenderness, skin changes
 - Age at first mammogram, dates and results of last mammogram, location of last mammogram
 - Previous breast surgery (date, physician, location, biopsy results)
 - Family history of breast or ovarian cancer and age at diagnosis (mother, daughter, sister)

2. Clinical Examination:

With the patient sitting or standing:

- Inspection for asymmetry, abnormal superficial vascular patterns, dimpling, nipple retraction, orange peel skin appearance (peau d'orange).
- Palpation of axillary and supraclavicular/infraclavicular nodes. Note size, location, mobility and consistency of nodes palpated.

With the patient supine:

- Repeat inspection procedure as above
- Repeat palpation procedure as above

D. Mammography Screening

1. Screening mammogram

- a. **Definition:** A screening mammogram is performed on asymptomatic women to detect early, clinically unsuspected breast cancer. (American College of Radiology)
- b. **Purpose:** The purpose of screening mammograms is to find breast cancers before they cause symptoms. Early detection results in the diagnosis of breast cancer before there are palpable masses and symptoms. Breast cancers found during screening examinations are more likely to be

small, confined to the breast, may not require chemotherapy or lymph node surgery, and increase the number of treatment options.

A screening mammogram consists of two views

Mediolateral Oblique (MLO)

Visualizes:

- ✓ Pectoral Muscle
- ✓ Breast
- ✓ Nipple
- ✓ Breast Tissue

Craniocaudal (CC)

Visualizes:

- ✓ Tissue missed on the MLO
- ✓ CC is more likely to show medial tissue

2. Diagnostic Mammogram

- a. **Definition:** A diagnostic mammographic examination is performed on a woman with clinical signs or symptoms that suggest breast cancer (American College of Radiology)
 - A second type of diagnostic examination is performed on women with an abnormal mammogram. (American College of Radiology)
 - Additionally, diagnostic mammograms are performed on women with augmented breasts, reconstructed breasts, and breast implants.
- b. **Purpose:** The purpose of diagnostic mammography is to identify the exact size and location of a breast abnormality, the surrounding tissue, and lymph nodes. A diagnostic mammogram sometimes requires extra views, spot compression, and magnification. Most diagnostic mammograms are likely to be benign. If an abnormality is suspicious, usually an ultrasound study follows and/or a biopsy may be ordered. If a woman has a clinically suspicious abnormality, a biopsy is the only way to determine with certainty whether she has breast cancer.

Note: (1) When scheduling a mammogram, previous films should be requested and sent to the contracted radiology facility. Films should be requested at least two weeks prior to the woman's appointment. (2) Results of the CBE and history of any prior breast surgery should also be included on the referral form to the radiology facility.

Breast Cancer and Mammography Information

According to the United States Cancer Statistics: 1999–2002 Incidence and Mortality Report, 182,125 new invasive cases of breast cancer were diagnosed among women in the United States in 2002, the most recent year for which statistics are currently available. Mammography is the best way to detect breast cancer in its earliest, most treatable stage—an average of 1–3 years before a woman can feel the lump. Mammography also locates cancers too small to be felt during a clinical breast examination.

Simply being a woman and getting older puts you at some risk for breast cancer. Your risk for breast cancer continues to increase over your lifetime.

Several factors can further increase your risk for breast cancer. For more information regarding these known risks contact the National Cancer Institute.

Source: U.S. Cancer Statistics Working Group. United States Cancer Statistics:
1999–2002 Incidence and Mortality Web-based Report. Atlanta:
U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National

NC BCCCP Guidance on Screening Mammography

Mammograms are provided for symptomatic women under 50 years of age who require diagnostic work-up. There is no consensus on guidance for this age group. Factors that influence this decision may be genetics, personal history, family history, first ordinal relative with a diagnosis, a previous biopsy showing benign conditions, ductal carcinoma in situ, or age 30 or older at the time of first birth.

The priority population for NBCCEDP mammography services is the group of women between the ages of 50 and 64 who are low-income (250% of federal poverty level or less) and who have not been screened in the past year. At the clinician's discretion, women age 50-64 with a history of normal screening results and no significant risk factors may be put on an every-other-year screening cycle.

NC BCCCP Screening Performance Age Requirements:

Indicator Type	Performance Indicator	National Breast and Cervical Cancer Early Detection Program (NBCCEDP)
Breast Cancer Screening	Screening mammograms to women 50 - 64 years of age every 1 - 2 years	At least 75% of all initial mammograms
Breast Cancer Screening	Mammograms provided for symptomatic women under 50 years of age who require a diagnostic work-up or who have a family history of breast cancer	No more than 25% of all initial mammograms

Mammography Age Guidance from Government and Professional Entities

Aside from genetics, personal and family history, there is no consensus on age for mammography screening, especially for women between the ages of 40 and 49. Listed below is a sampling of various government and health care organizations and their guidance.

Recommends counseling about potential risk and benefits of mammography for women ages 40 to 49

- American Academy of Family Physicians

Recommend an annual mammogram beginning at age 40

- American Academy of Family Physicians
- American Cancer Society
- American College of Radiology
- American College of Surgeons

Recommend a mammogram every 1 - 2 years for women 40 - 49 years of age

- American College of Obstetricians and Gynecologists
- American Medical Association
- American Medical Women's Associations
- National Cancer Institute

Recommend that women under the age of 50 not be screened

- American College of Physicians

State there is insufficient evidence to recommend for or against routine screening for women under 50 years of age

- U.S. Preventive Services Task Force
- American College of Preventive Medicine

Recommend annual mammograms for women 50 years of age and older

- American Cancer Society
- American College of Obstetricians and Gynecologists
- American College of Radiology
- American College of Surgeons

-
- American Medical Association
 - American Medical Women's Association

A mammogram every 1 to 2 years for women 50 and older

- National Cancer Institute
- American Academy of Family Physicians
- American College of Physicians
- American College of Preventive Medicine
- U.S. Preventive Services Task Force

How to do a Breast Self-Exam

Step 1

Look for changes in front of a mirror.



a.

Stand in front of a mirror in which you can see to your waist.

- As you look at your breasts, keep your arms relaxed at your sides.
- Look for changes in shape and color.
- Check the front and turn from side to side. Look for:

- puckering
- dimpling
- skin changes
- scaliness
- any nipple discharge

- If your breasts are large, lift each one up to see underneath.



b.

Raise your hands above your head.

- Check the front and turn from side to side.
- Lean forward, bending at the waist, and check as you did before.



c.

Place your hands on your hips and press down.

- Check front and each side as you did before.

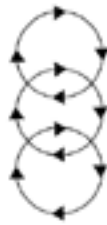
Step 2

Getting Started.



d. Use the pads of your fingers.

- Use the pads of your 3 middle fingers
- Do not use fingertips
- Keep your fingers together



Use dime-size circles

Move your fingers in 3 dime size circles, one at each of the levels of pressure.



3 levels of pressure are important

Use 3 levels of pressure in each spot:

1. light (just moves skin)
2. medium
3. deep (you may feel your ribs)

Use the vertical strip

Use a vertical strip pattern (like cutting the grass or vacuuming the carpet) to check all your breast tissue. Include area under the nipple. Do not squeeze the nipple.



Step 3

Feel for changes lying down.

You will lie down on your bed or other firm surface.

You will need to examine all your breast tissue (the shaded part on the drawing).

All your breast tissue is:

From your armpit to lower bra line > across to the center of the chest > up to the collar bone and across > back to the deepest part of the armpit



e.

Check your right breast with your left hand

- Lie on your left side. Roll your right shoulder back towards the bed.
- Raise your right arm above your head, and put the back of your right hand on your forehead.

• Begin under your arm in the deepest part of your armpit.

- Make dime-size circles at each of the 3 levels of pressure (light, medium, deep) in that spot.



- Then extend the outer finger of the 3 fingers and move one finger width. Make 3 more circles of pressure.

- Continue to do this as you go down the vertical strip to your lower bra line.

- Then move over a finger's width and go back up your breast to your underarm.

- Go up and down your breast in strips until you get to the center of your chest or breast bone.

- The nipple area will be checked using the same pattern as the rest of the breast tissue. If you have large breasts, roll onto your back when you reach the nipple. Do not squeeze the nipple!



f.

You are now ready to check your left breast with your right hand

- Lie on your right side. Roll your left shoulder back towards the bed.
- Raise your left arm above your head, and put the back of your left hand on your forehead.

- Do just as you did with your right breast - you begin at the top of your armpit.

Check above and below the collarbone for any swelling or lumps.

This completes your breast self-exam.

If you see or feel any skin changes or lumps be sure to tell your doctor or nurse right away.

Don't forget to do your breast self-exam each month!

Autoexamen De Los Senos

Paso 1 Busque cambios frente al espejo.

a. Parada frente a un espejo donde pueda mirarse hasta la cintura.

- Observe sus senos, mantenga los brazos relajados, a lo largo del cuerpo.

- Busque cambios en la forma y el color.
- Mírese de frente y de ambos costados.

Lo que debe buscar:

- retracción de la piel
- cambios en la piel
- alguna secreción que salga del pezón
- Si sus senos son grandes, levante cada uno para mirar la parte de abajo.



b. Levante los brazos sobre la cabeza.

- Mírese de frente y de lado a lado.
- Inclínase un poco al frente, doblandose por la cintura, y mírese como lo hizo antes.



c. Con las manos en las caderas presione hacia abajo.

- Mírese de frente y de lado a lado como lo hizo antes.



Paso 2 Cómo empezar.

d. Use la yema de los dedos

- Use la yema de los 3 dedos del medio
- No use la punta de los dedos
- Mantenga los dedos juntos



Mueva los dedos en círculos

Cada uno en un movimiento circular del tamaño de una moneda de 10 centavos, a los tres niveles de presión.



Los 3 niveles de presión son importantes

- Use 3 niveles de presión en cada punto:
1. leve (solo mueva la piel)
 2. media
 3. profunda (siente las costillas)



Use el patrón de franja vertical

Siga un patrón de franja vertical (como al cortar el césped o usar la aspiradora) para revisar todo el tejido del seno. Continúe de esta manera sobre toda el área del seno y el pezón. No apriete el pezón.



Paso 3 Palpe para ver si siente cambios mientras está acostada.

Recuéstese en la cama o en otra superficie firme.

Es necesario que examine todo el tejido mamario (la parte sombreada en el dibujo).

Todo el tejido mamario de su seno va:

Desde la parte media de su axila hasta la línea inferior del sostén > cruzando hasta el centro del pecho > subiendo hasta la clavícula y cruzando > hasta la parte media de la axila



e.

Palpe su seno derecho con la mano izquierda

- Recostada sobre su lado izquierdo. Gire el hombro derecho hacia la cama.
- Levante el brazo derecho, colóquese la mano derecha en la frente, con la palma hacia arriba.
- Contrócese debajo del brazo (axila).
- A medida que avanza haga 3 pequeños círculos del tamaño de una moneda de 10 centavos aplicando los 3 niveles de presión (leve, media, profunda) en cada punto que examine.



- Luego, extienda el dedo que queda más afuera (de los 3 dedos) y bajela anchura del dedo. Haga otros 3 círculos aplicando presión.
- Continúe este movimiento según va bajando hasta la línea inferior del sostén.
- Luego mueva los dedos tanto como el ancho de un dedo y suba por el seno hasta llegar a la axila.

- Siga subiendo y bajando por el seno en franjas hasta llegar al centro del pecho.
- El pezón se examina usando el mismo patrón que el resto del tejido del seno. Si sus senos son grandes, acuéstese de espaldas para alcanzar el pezón. ¡No apriete el pezón!



f.

Ahora, puede examinar el seno izquierdo con la mano derecha.

- Recostada sobre su lado derecho. Gire el hombro izquierdo hacia la cama.
- Levante el brazo izquierdo, colóquese la mano izquierda en la frente, con la palma hacia arriba.
- Haga lo mismo que hizo con el seno derecho; comience en la parte superior de la axila.

Examine el área encima y debajo de la clavícula, por si tuviera alguna hinchazón o bulto.

Con esto completa su autoexamen de los senos.

Si usted ve o siente algún cambio en la piel, le sale líquido del pezón o siente algún bulto, informe a su médico o enfermera de inmediato.

¡No se olvide de hacer el autoexamen de los senos todos los meses!



El Programa para el Control del Cáncer de Seno y el Cáncer Cervical Está Aquí para Servirle.

Clinical Breast Examination Procedure

The purpose of the clinical breast examination (CBE) is to assess breast health status. A CBE should be thorough. The examination may be done as part of a general exam or as a separate exam for asymptomatic or symptomatic women. Establishing rapport with the patient prior to the CBE helps the patient relax. Review the patient's health history and any current symptoms.

The results of the examination should be well documented in the medical record with a diagram to note any clinical findings. Failure to track and to notify a patient who needs additional diagnostic studies or treatment services puts these women at increased risk.

Components of the Examination:

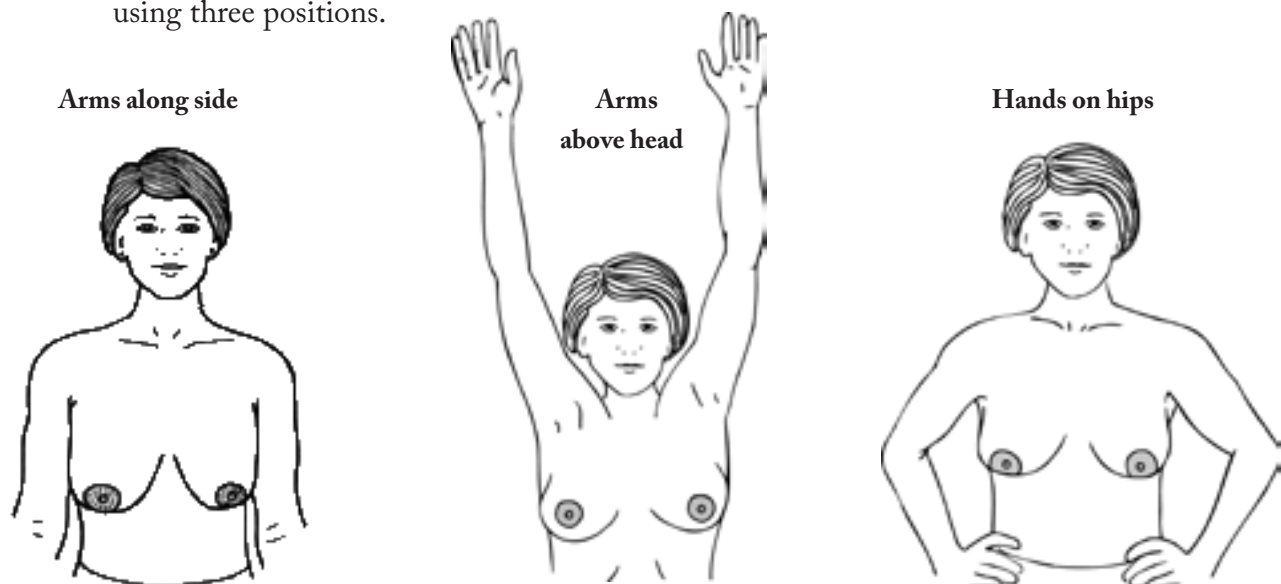
- A. Patient education
- B. Visual inspection
- C. Palpation of the lymph nodes
- D. Palpation of the entire perimeter of breast tissue

E. Patient Education

Assess the patient's level of knowledge about self-breast examination. Acknowledge, elicit and discuss patient fears or beliefs regarding screening procedures. A handout on How to Do a Breast-Self Exam is available on page I-10.

F. Visual Inspection

While the patient is sitting visually inspect the breasts with both frontal and lateral views using three positions.



Inspect for the following:

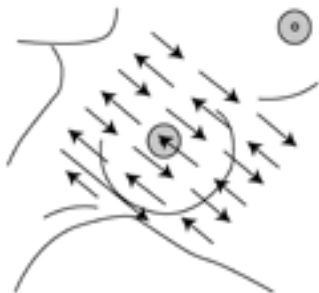
- changes in breast symmetry and contour ;
- changes in skin texture or color;
- signs of infection;
- dryness or scaliness of the nipple/areolar complex; and
- skin retraction or dimpling.

G. Palpation of the lymph nodes

Palpate the lymph nodes in the supraclavicular, infraclavicular and axillary areas. Assess for nodal enlargement that may indicative of infection or cancer metastasis. Refer to page I-15 more information on examination of lymph nodes.

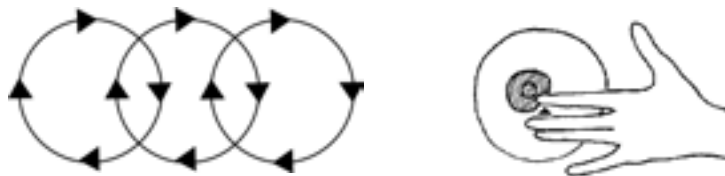
H. Palpation of the entire perimeter of breast tissue

- 1) Palpate the entire perimeter of the breast tissue using the vertical strip method as shown in the following diagram. The breast tissue is examined in a roughly rectangle area. The exam should begin in the mid-axillary line and moves downward.

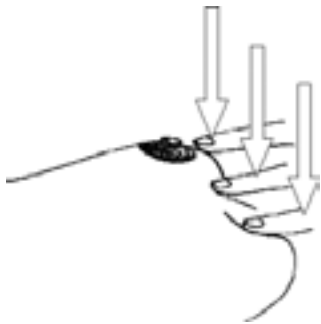


The exam area extends down from the middle of the underarm to just beneath the breast, continues across the underside of the breast (fifth rib), continues across the underside of the breast to the middle of the breast bone, then moves up the sternum, along the collar bone, and back to the middle of the underarm.

Palpate using the pads, not tips, of the three middle fingers, with the hand bowed slightly. The pads of the fingers are the most sensitive. The fingers should move in dime-size circles using three levels of pressure. Palpations should overlap slightly to ensure a thorough examination of all tissue.



Using three sequential depths of pressure in overlapping dime-size circles allows detection of asymmetrical thickening or masses at different tissue depths.



- Light or superficial pressure allows evaluation of the breast surface
- Medium pressure depth palpates middle structures and
- Deep circles of pressure evaluates tissue next to the chest wall

Solicit patient feedback to reduce discomfort during the exam. This will also reinforce patient understanding about performing Breast Self Exams.

The examiner should position the patient on her side to begin palpation. Have her roll opposite the breast you are going to examine. The patient places her hand on her forehead and rolls her shoulder back so the nipple is midline. This flattens the breast tissue that would have been on her side if she were lying on her back.



When you palpate to the nipple, have the patient turn on her back and place her arm at a right angle with her hand behind her head. This will flatten the medial portion of the breast to allow comprehensive palpation of all breast tissue. When you are ready to examine the lateral part of the breast, have the patient position on her other side as you did in the beginning.

Document any abnormal findings of the clinical breast exam using three characteristics:

- Is the mass or nodule hard or soft?
- Is the mass or nodule movable or fixed?
- How large is the mass or nodule?

Refer to section IV of the Breast Screening Manual for Management of Abnormal Clinical Findings.

EXAMINATION OF THE LYMPH NODES

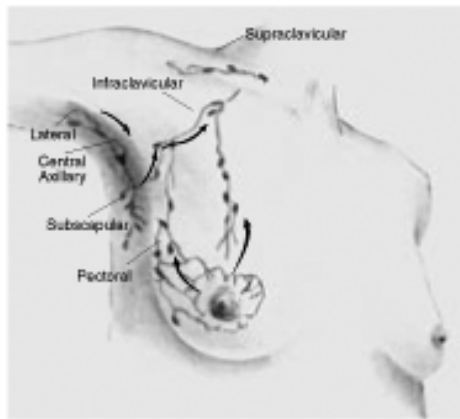


Figure 1

Lymph Drainage of the Breast (Figure 1)

Seventy-five percent of the lymphatic drainage from the breast is into the axillary nodes. Lymph from 3 groups of axillary nodes, the lateral, the subscapular and the pectoral, drain into the central nodes that are high in the axillae. These nodal groups are also referred to as **Level I** (low axilla), **Level II** (mid-axilla) and **Level III** (apical axilla), as described in surgical or pathology reports.

Positioning for the Exam

The patient should be in a seated position for both the clavicular and axillary exam to optimize deep palpation. Lying down with the hand over the head tenses the axilla. Before examining the patient, explain the rationale and what you are looking for.



Figure 2

Palpation of the Supraclavicular and Infraclavicular Nodes (Figure 2)

- Using firm pressure in small circular movements, palpate above and below the clavicle.



Figure 3

Palpating the Axillary Nodes (Figure 3)

- Instruct the patient to drop the shoulder and take a deep breath to facilitate relaxation.
- Support the patient's arm and elbow with the non-examining hand to maintain optimal relaxation.





Figure 4a

Palpation of the Axillary Nodes

(Figure 4a)

Axillary nodes are palpated at deep pressure using a circular motion with the pads of the three middle fingers of the examining hand, in all four aspects of the axilla. Note that this pattern resembles a *diamond*.

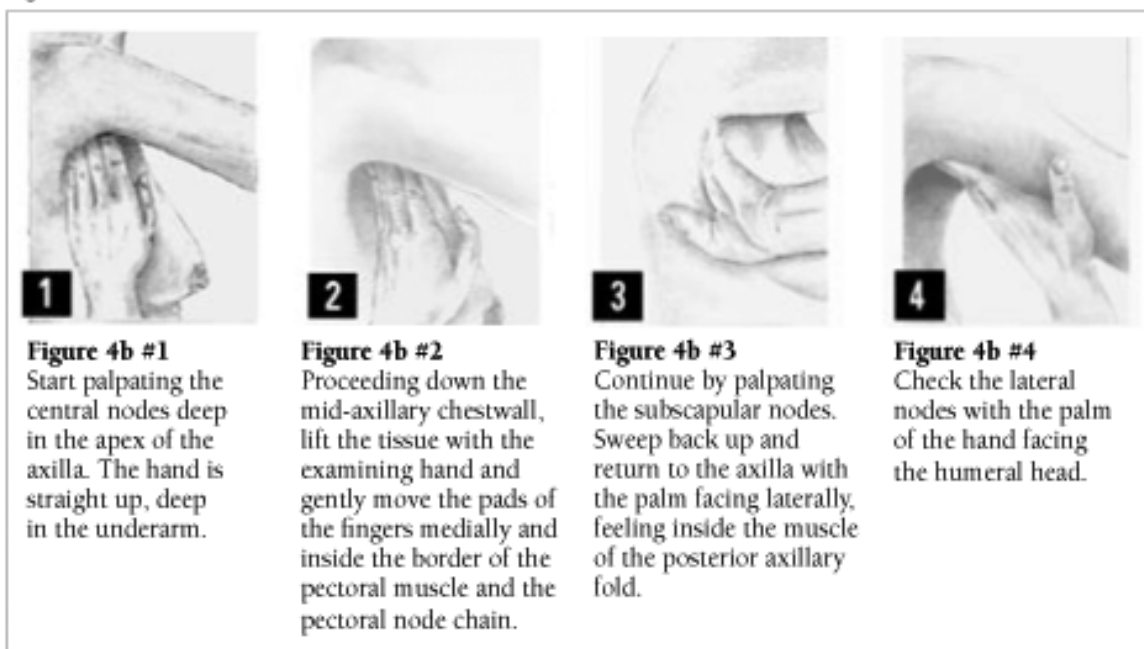


Figure 4b

Findings

Shotty nodes are usually small and less than 1cm, soft, mobile and of little clinical significance. Nodes that suggest inflammation or infection, or are fixed, matted or persistent, should be considered a suspicious finding. Note the size, shape, firmness and mobility. Appropriate follow-up may include mammography, ultrasound or other tests as indicated by history and clinical findings.

References

- Bates, B. (1995). *Physical Examination and History Taking 6th Edition*. Philadelphia, JB Lippincott
- Gray, Henry. (2000). *Gray's Anatomy In Chapter: Lymphatics of the Upper Extremity, 15th Edition*. New York, Barnes& Noble Publishers.
- Harris, J; Lippman, M; Morrow, M & Hellman, S. (1996). *Diseases of the Breast*. In Chapter 1: Breast Development & Anatomy, Philadelphia, Lippincott-Raven



Quality Assurance Recommendations for Breast Cancer Screening

For breast cancer screening to be effective, health care providers need to have systems in place to ensure that any abnormalities detected by clinical breast exam or mammography are appropriately followed up. Notify patients of abnormal test results promptly. Track patients who need additional diagnostic tests results or treatment to assure they get proper follow-up care.

Five key steps are necessary for managing the results of breast cancer screening:

- 1) Track any imaging studies until results are obtained;
- 2) Follow requirements for patient notification (see page II-3);
- 3) Document that notification has occurred;
- 4) Refer patients with any abnormalities on clinical breast exam or imaging for appropriate follow-up; and
- 5) Track referrals to make sure that patients have actually received follow-up.

Each clinic might have a different mechanism for ensuring that all of these steps have occurred, but all clinics should have written guidelines, standards, and policies for management of breast cancer screening programs. Written policies must be accessible to staff. This manual contains recommendations that should be considered in the development of local policies. Policies should be reviewed at least annually and revised as needed.

The following integral elements are required for a follow-up system.

1. **Designation of a responsible person:** The person designated as having responsibility for follow-up of breast cancer screening should be a nurse who has knowledge of breast cancer screening programs and familiarity with guidelines regarding follow-up of patients with abnormal breast cancer screening results.
2. **A referral plan:** The referral plan will contain written procedures for referring patients with abnormal findings, including referral resources, the process of referring, and the preparation of eligibility forms, if applicable. All education and counseling protocols should be included, along with a list of educational materials used to assist the patient in understanding the abnormal test result or any additional diagnostic tests that may be done.
3. **A follow-up plan:** The follow-up plan will contain written procedures that ensure the patient was referred to a provider, needed services were provided, and the results of the referral were returned to the agency.
4. **A tracking system:** Clinical management of patients is improved with a tracking system. Ticker files, computerized databases or written logs are common methods of tracking patients. The system alerts staff of patients' status, especially abnormal breast screening, and provides a simple tool for follow-up. Any tracking system must be checked at

predetermined intervals to ensure follow-up is completed. The following is a suggested general process for breast screening tracking:

- All mammograms ordered are logged into a tracking system.
- When results are received by the agency, the person responsible for follow-up reviews the reports.
- Results requiring no intervention require patient notification. The report is initialed by the nurse or designee and filed in the medical record.
- Results requiring follow-up are reviewed, the patient is notified, and the plan of care is determined based on this manual, local policy, and consultation with the medical advisor.
- The plan of care and notification of the patient are documented in the medical record.
- The nurse responsible for patient follow-up enters information in the tracking system and monitors the progress of the patient until follow-up is complete.

Tracking Systems Remind Staff to:

- Document all patient contacts.
 - See tests and examinations ordered and compare to tests with no results.
 - Review patients with incomplete interval follow-up (monthly, quarterly, etc.).
 - Develop procedures to overcome patient-related barriers to follow-up, for example, telephone reminders, mailing reminders.
 - Attempt to contact patients three times to assure that patients are receiving treatment.
 - Use Certified Mail at the third attempt to notify patients.
5. Internal quality assurance: Periodically, chart audits should be performed to track the percent of women with abnormal results who receive definitive diagnostic and therapeutic procedures. Documentation of findings and corrective action should be on file.

Patient Notification Requirements

Mammography Quality Standards Act (MQSA)

MQSA requires the radiology facility that performed the mammogram to send the provider a report of the examination and send the patient a lay letter of the examination.

In addition if the mammogram is interpreted as either

Category 4 - Suspicious or

Category 5 - Highly Suggestive of Malignancy, the following are also required:

- The facility is required to notify the patients and health care providers of positive examinations as soon as possible (as guidance, within 5 and 3 business days respectively). In the case of verbal communication, this may be done by documenting such communication in the mammography report or in logs. In the case of written communication, see two bulleted items below:
- The facility is required to send a written mammography report. This may be done by having copies of the mammography report available within 30 days of the examination (positive mammography reports should be available within 3 business days).
- The facility is required to send written lay summaries to the patients themselves. This may be done by having copies of the lay summary available within 30 days of the examination (positive lay summaries should be available within 5 business days). If the facility does not keep copies of the patients' lay reports, they may document such communication in the mammography report, or in logs, or by stating in the facility's Quality Assurance (QA) manual that the lay summary is provided within the appropriate time frames.

NC Breast and Cervical Cancer Control Program Quality Assurance

A. Responsibilities of all Breast Screening Providers

- Notify patients who have normal (negative) mammograms of their results.
- Ensure follow-up of abnormal screening results with the patient.
- All results from any referral will be documented in the patient's medical record.
- Documentation will include all contacts with patients regarding appointments for referral and appointments not kept.

B. Additional Responsibilities of NC BCCCP Contractors

- The contractor assures follow-up on patients with abnormal screening results is completed within 60 days of the patient's initial screening examination.

-
- Three attempts are required to contact patients with abnormal screening results. The third attempt to notify a patient with abnormal screening results must be by certified mail.
 - The NC BCCCP clinical standards of care will be used to manage abnormal test results. Contracts with outside medical providers will specify program expectations.
 - All NC BCCCP-eligible women, who have abnormal results for any NC BCCCP covered test, are followed by the BCCCP Coordinator until a qualified provider determines that the patient does not have cancer or until the patient is under care for a diagnosed cancer.
 - The follow-up process includes correct entry of clinical information to support NC BCCCP's requirements for CDC for submission and timely data reports.
 - The follow-up process also includes a local protocol that recalls the BCCCP patient for appropriate re-screening for breast and cervical cancer.

Management of Abnormal Clinical Findings

If an abnormality is found on clinical breast examination or screening mammography, further diagnostic workup is necessary to diagnose the nature of the abnormality. An algorithm that summarizes key management decisions is provided.

I. The Palpable Mass

Any patient with a solid, well-defined palpable mass should be referred for breast imaging AND further evaluation by a surgeon with expertise in breast evaluation.

Women who are older than 30 years old should be referred for a diagnostic mammogram. Mammograms can be more difficult to interpret after diagnostic procedures such as fine needle aspirations, so it should be ensured that the mammogram appointment takes place prior to surgical evaluation. The location and nature of any breast abnormality detected on examination should be noted on the mammogram referral.

Women who are 30 years old or younger should be referred for breast ultrasound. Again, the imaging should take place prior to surgical evaluation, and abnormal findings on breast examination should be noted on the ultrasound referral.

Referral to a surgeon should occur even if breast imaging (mammogram and/or breast ultrasound) is normal, except in a few well-defined situations described below. A negative mammogram in a patient with a palpable mass does not rule out breast cancer.

Mammography may miss up to 10 - 20 percent of cancers in women with dense breasts. When a patient has an area of palpable concern that is limited by dense tissue, and the mammogram and spot compression magnification are unremarkable, ultrasound is performed. A study published in 2001 showed “a high negative predictive value (99.8%) for sonography and mammography in the setting of a palpable lump, which should assist the referring physician in decision-making and support clinical follow-up rather than biopsy for palpable lesions that are not clinically suspicious.”¹

¹Soo MS, Rosen EL, Baker JA, Thuy TV, Blythe AB, Negative predictive value of sonography with mammography in patients with palpable breast lesions. *American Journal of Roentgenology* 2001; 177: 1167-1170.

Procedures a woman might undergo when referred to a surgeon include fine needle aspiration, core needle biopsy, or surgical excisional biopsy. Fine needle aspiration (FNA) is particularly useful for a patient in whom it is suspected that a breast mass is a simple cyst. The procedure consists of inserting a 22-24 gauge needle into the mass and removing any fluid the mass contains. Fluid can be sent for laboratory analysis to assess for malignancy. Core needle biopsy consists of inserting a larger gauge needle into the mass and removing tissue for evaluation by a pathologist. Excisional biopsy consists of surgically removing the entire mass.

II. Non-palpable Masses Found on Mammography

Abnormalities on mammography are categorized according to a system designed by the American College of Radiology called BI-RADS® or the Breast Imaging Reporting and Data System. A mammogram report will contain one of six designations:

Category 0: Needs Additional Imaging Evaluation

Category 1: Negative

Category 2: Benign Finding

Category 3: Probably Benign Finding

Category 4: Suspicious Abnormality

Category 5: Highly Suggestive of Malignancy

Patients with normal breast exams whose mammograms report Category 1 or 2 findings do not require further follow-up and can be rescreened in one to two years.

Patients with mammograms that report Category 0 or 3 findings should follow-up as suggested by the radiologist's recommendations. This might include immediate referral for additional imaging, referral for additional imaging at a later date, or referral to a surgeon for biopsy.

Patients with mammograms that report Category 4 or 5 findings should always be referred to a surgeon. This referral should take place within five business days. The results of the mammogram should be made available to the surgeon to whom the patient is referred.

A sample mammography report, with instructions for interpretation, is provided on page IV-1.

III. Vague Thickening or Nodularity Not Suspicious for Cancer

For premenopausal women with vague thickening not suspicious for cancer, it is appropriate to repeat clinical breast examination mid-cycle after one or two menstrual cycles. If a localized area remains abnormal on repeated examination, the patient should be referred to a surgeon for evaluation. Mammography is ordered in such women just as described above under "The Palpable Mass."

Postmenopausal women with a questionable clinical breast examination should be referred for imaging and surgical evaluation according to the recommendations above under "The Palpable Mass."

IV. Nipple Discharge or Skin Changes

The nature of nipple discharges should be defined by a careful history. A patient with a spontaneous bloody discharge should be referred to a surgeon. Bilateral milky nipple discharge

is almost always benign. Medical work-up of galactorrhea may be appropriate for profuse or persistent milky discharge.

Patients with any skin breakdown on the nipple-areola complex should be referred to a surgeon. Biopsy of the nipple may be necessary to differentiate eczema of the nipple from Paget's disease (cancer of the nipple).

V. Breast Pain

Breast pain includes any discomfort or pain of the breast, such as premenstrual tenderness. Breast pain is typically benign. The question is how tolerable (or intolerable) the pain is for the woman. There are many causes of breast pain, including hormonal fluctuations related to menstruation or pregnancy, where some degree of pain is normal. With menopause breast tenderness often goes away, unless a woman is taking hormone replacement therapy.

Other causes of breast pain include fibrocystic breast changes, mastitis (blocked or infected milk duct), premenstrual syndrome (PMS), alcoholism with liver damage, and injury. There are certain medications that cause breast pain, including digitalis preparations, aldomet, aldactone and other potassium-sparing diuretics, anadrol and chlorpromazine.

If the clinical breast examination is normal, reassure the patient and explain the hormonal causes of breast pain. Typically the patient's mind is put at ease. A trial of non-narcotic analgesics such as acetaminophen (Tylenol) or ibuprofen (Advil, Motrin), the use of a well-fitting bra which provides good support, or the use of a warm liquid heat is also suggested. Although there is no clear evidence in the literature that shows reducing dietary caffeine, salt, or fat improves breast pain, some women report benefits from these changes. These recommendations may be suggested for women with breast pain. If the pain persists, a repeat breast exam and mammogram may be provided.

If the follow-up breast examination and screening mammogram are normal and breast pain persists, refer the woman to a breast specialist for further evaluation. For women with breast pain who have a palpable mass or mammographically detected abnormality, the work-up is identical to that of women with palpable mass. Though breast cancers are usually painless, the presence of pain cannot reliably rule out breast cancer. There are a small percentage of breast cancers that present as painful or uncomfortable.

VI. Special Considerations

Fibrocystic Breasts - Fibrocystic changes are the most common cause of non-cancerous breast lumps. They affect at least 50% of women at some point in their lives, most commonly between the ages of 30 and 50. Fibrocystic breasts are usually not a risk factor for breast cancer, but women with fibrocystic breasts may have diffusely lumpy breasts, making detection of

underlying breast cancer more difficult. If there is any uncertainty about clinical breast exam in a patient with fibrocystic breasts, the patient may be referred for mammography, ultrasound and/or a consultation with a breast specialist.

Fibroadenoma - A noncancerous rubbery lump in the breast that is painless and moves around easily when touched. Fibroadenomas cannot be diagnosed with mammography, sonography, or histopathology. Fibroadenomas can only be diagnosed with a biopsy.

Pregnant and Lactating Women - These women often experience breast tenderness and engorgement, which can make detection of masses more difficult. Lactating women should empty their breasts prior to a CBE or mammogram. If an abnormality is found, diagnostic evaluation with mammography and ultrasound may be used. Mammography poses little risk of radiation if the woman is properly shielded. However, mammograms should only be used to evaluate distinct, dominant masses. The radiologist should always be informed if the woman is pregnant. A referral to a breast surgeon should be made for a definitive diagnosis.

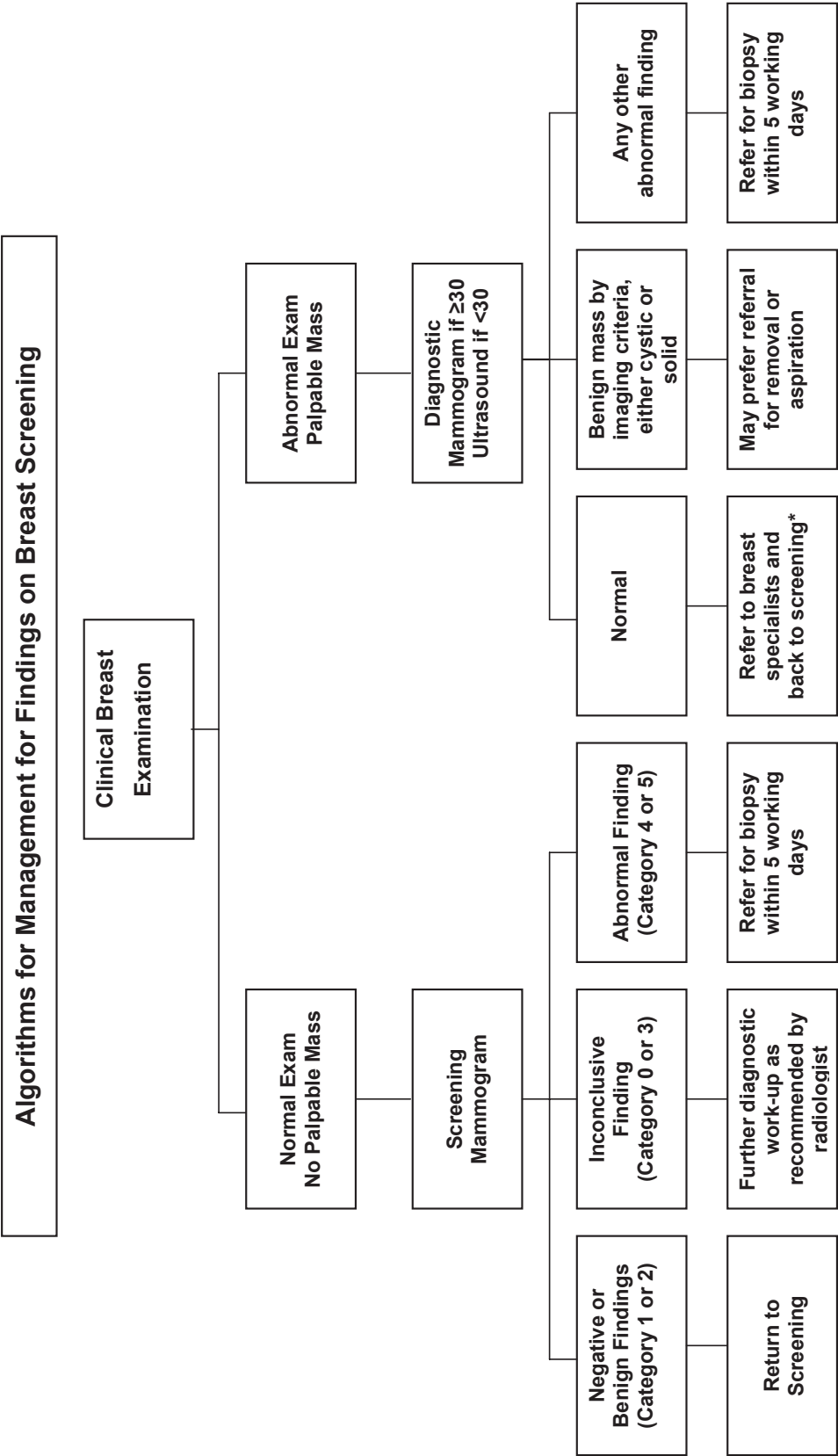
Other Patients with a Difficult Breast Examination

Some women may have a difficult clinical examination which requires further evaluation. This group may include:

- Women who have had breast reduction surgery
- Women with multiple previous biopsies and scarring
- Women with breast implants
- Women who have had a mastectomy

If a clinician is unsure of the significance of findings on clinical examination in any of the above situations, a referral to a mammography or breast specialist should be made.

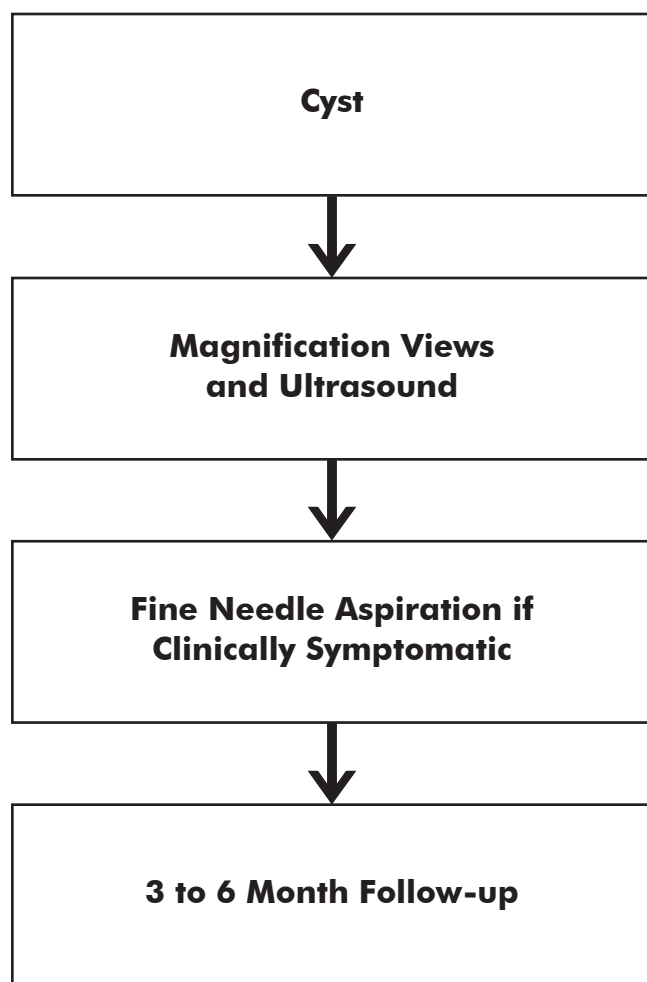
Algorithms for Management for Findings on Breast Screening on Breast Screening



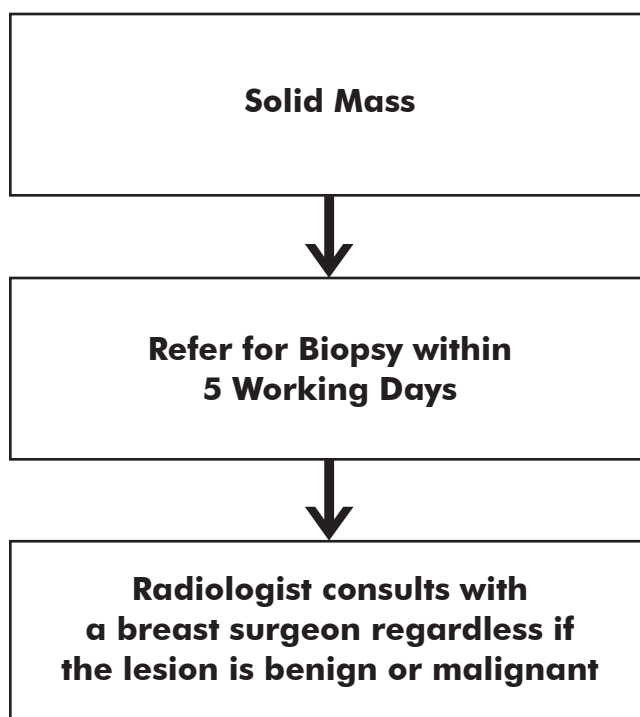
*BCCCP required that all palpable masses be referred for a diagnostic work-up.

Algorithm on Managing Palpable Masses

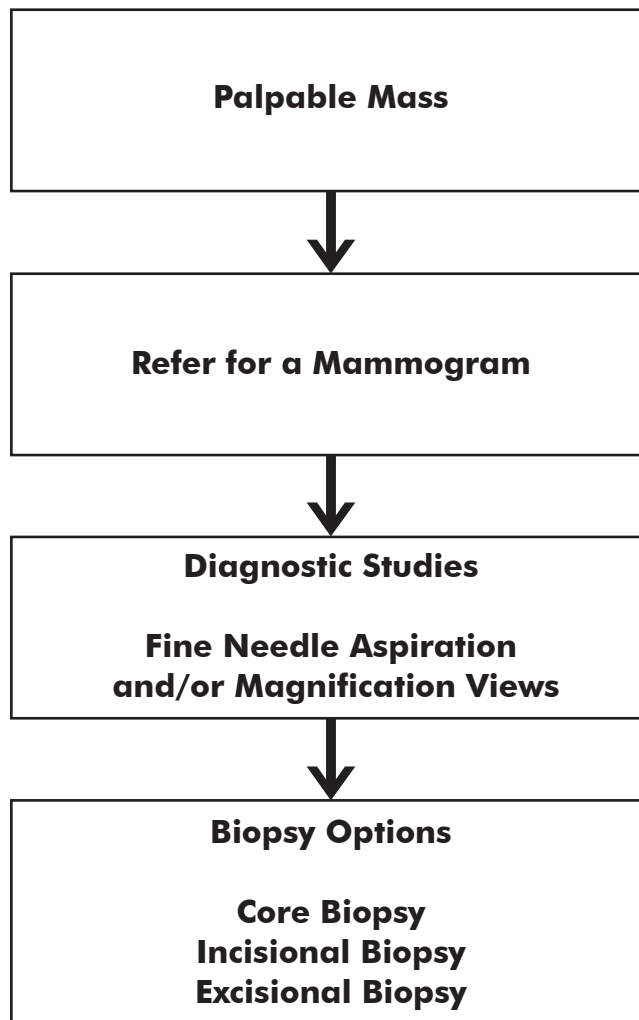
Managing Palpable Masses



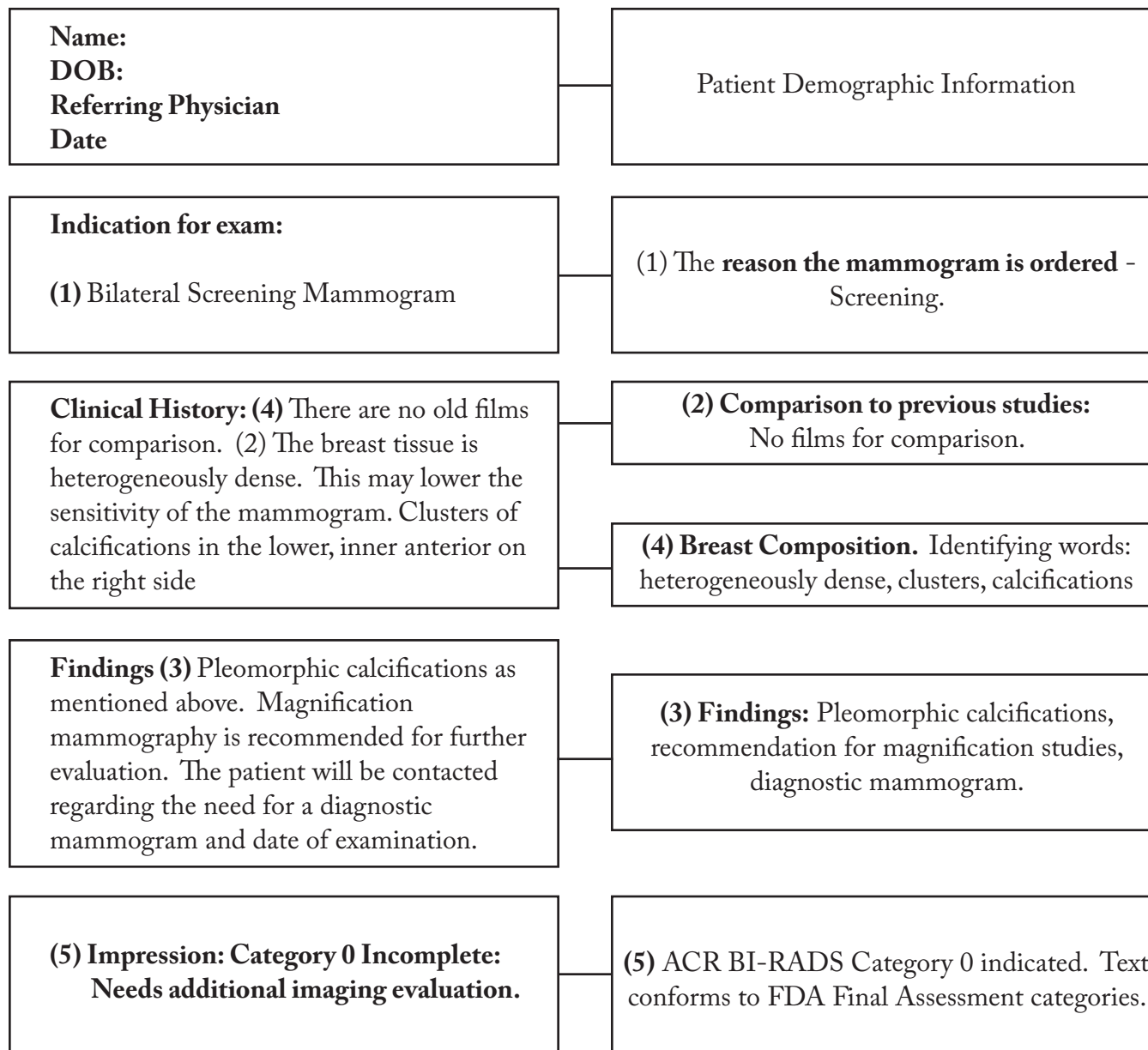
Managing Non-Palpable Masses Seen on Screening Mammogram



Algorithm on Managing a Fibroadenoma



Organization of the Mammography Report



FDA FINAL ASSESSMENT CATEGORIES REQUIRED

Category 0 - Incomplete: Needs Additional Imaging Evaluation
 Category 1 - Negative
 Category 2 - Benign
 Category 3 - Probably Benign
 Category 4 - Suspicious
 Category 5 - Highly Suggestive of Malignancy

American College of Radiology Breast Imaging and Reporting Data System BI-RADS® Atlas

Assessment Categories

Mammography Assessment Is Incomplete

Category 0

Needs Additional Imaging Evaluation and/or Prior Mammograms for Comparison:

Finding for which additional imaging evaluation is needed. This is almost always used in a screening situation. Under certain circumstances this category may be used after a full mammographic work-up. A recommendation for additional imaging evaluation may include, but is not limited to, the use of spot compression, magnification, special mammographic views and ultrasound.

Whenever possible, if the study is not negative and does not contain a typically benign finding, the current examination should be compared to previous studies. The radiologist should use judgment on how vigorously to obtain previous studies. Category 0 should only be used when awaiting old films for comparison when such comparison is **required** to make a final assessment.

Mammographic Assessment Is Complete - Final Categories

Category 1

Negative:

There is nothing to comment on. The breasts are symmetric and no masses, architectural distortion or suspicious calcifications are present.

Category 2

Benign Finding(s):

Like Category 1, this is a “normal” assessment, but here, the interpreter chooses to describe a benign finding in the mammography report. Involuting calcified fibroadenomas, multiple secretory calcifications, fat-containing lesions such as oil cysts, lipomas, galactoceles and mixed-density hamartomas all have characteristically benign appearances, and may be labeled with confidence. The interpreter may also choose to describe intramammary lymph nodes, vascular calcifications, implants or architectural distortion clearly related to prior surgery while still concluding that there is no mammographic evidence of malignancy.

Note that both Category 1 and Category 2 assessments indicate that there is no mammographic evidence of malignancy. The difference is that Category 2 should be used when describing one or more specific benign mammographic findings in the report, whereas Category 1 should be used when no such findings are described.

Category 3

Probably Benign Finding - Initial Short-Interval Follow-Up Suggested:

A finding placed in this category should have less than a 2% risk of malignancy. It is not expected to change over the follow-up interval, but the radiologist would prefer short-term follow-up to establish its stability.

There are several prospective clinical studies demonstrating the safety and efficacy of initial short-term follow-up for specific mammographic findings.

Three specific findings are described as probably benign (the noncalcified circumscribed solid mass, the focal asymmetry and the cluster of round [punctate] calcifications; the latter is anecdotally considered by some radiologists to be an absolutely benign feature). All published studies emphasize the need to conduct a complete diagnostic imaging evaluation before making a probably benign (Category 3) assessment; hence it is inadvisable to render such an assessment when interpreting a screening examination. Also, all the published studies exclude palpable lesions, so the use of a probably benign assessment for a palpable lesion is not supported by scientific data. Finally, evidence from all the published studies indicates the need for biopsy rather than continued follow-up when most probably benign findings change in size or extent.

While the vast majority of findings in this category will be managed with an initial short-term follow-up (6 months) examination followed by additional examinations until longer-term (two years or longer) stability is demonstrated, there may be occasions when biopsy is done (patient wishes or clinical concerns).

Category 4

Suspicious Abnormality - Biopsy Should Be Considered:

This category is reserved for findings that do not have the classic appearance of malignancy but have a wide range of probability of malignancy that is greater than those in Category 3. Thus, most recommendations of breast interventional procedures will be placed within this category. By subdividing Category 4 into 4A, 4B and 4C as suggested in the guidance chapter [Increasing levels of suspicion], it is encouraged that relevant probabilities of malignancy be indicated within this category so the patient and her physician can make an informed decision of the ultimate course of action.

Category 5

Highly Suggestive of Malignancy - Appropriate Action Should be Taken: (Almost certainly malignant.)

These lesions have a high probability (> 95%) of being cancer. Current oncologic management requires percutaneous tissue sampling as, for example, when sentinel node imaging is included in surgical treatment or when neoadjuvant chemotherapy is administered at the outset.

Reprinted with permission of the American College of Radiology. No other representation of this material is authorized without expressed, written permission from the American College of Radiology.

Breast Cancer Glossary

A

Abnormal

Not normal. An abnormal lesion or growth may be cancerous, premalignant (likely to become cancer), or benign.

Abscess

An enclosed collection of pus in tissues, organs or confined spaces in the body. An abscess is a sign of infection and is usually swollen and inflamed.

Adenoma (ad-in-O-ma)

A noncancerous tumor.

Adjunct agent

In cancer therapy, a drug or substance used in addition to the primary therapy.

Adjuvant therapy (AD-joo-vant)

Treatment given after the primary treatment to increase the chances of a cure. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, or biological therapy.

Areola (a-REE-o-la)

The area of dark-colored skin on the breast that surrounds the nipple.

Aspiration (as-per-AY-shun)

Removal of fluid or tissue through a needle.

Axilla (ak-SIL-aa)

The underarm or armpit.

Axillary dissection (AK-suh-LAIR-ee dis-EK-shun)

Surgery to remove lymph nodes found in the armpit. Also called axillary node dissection.

Axillary lymph node (AK-suh-LAIR-ee)

A lymph node in the armpit region that drains lymph channels from the breast.

Axillary lymph node dissection (AK-suh-LAIR-ee dis-EK-shun)

Surgery to remove lymph nodes found in the armpit region. Also called axillary dissection.

B

Benign (beh-NINE)

Not cancerous. Benign tumors may grow larger but do not spread to other parts of the body.

Benign breast disease (beh-NYN breast dih-ZEEZ)

A common condition marked by benign (noncancerous) changes in breast tissue. These changes may include irregular lumps or cysts, breast discomfort, sensitive nipples, and itching. These symptoms may change through the menstrual cycle and usually stop after menopause. Also call fibrocystic breast disease, fibrocystic breast changes, and mammary dysplasia.

BI-RADS

Breast Imaging Reporting and Data System. A method used by radiologists to interpret and report in a standardized manner the results of mammography, ultrasound, and MRI used in breast cancer screening and diagnosis.

Bilateral

Affecting both the right and left sides of the body.

Bilateral prophylactic mastectomy (by-LAT-uh-ral pro-fi-LAK-tik mas-TEK-tuh-mee)

Surgery to remove both breasts in order to reduce the risk of developing breast cancer. Also called preventive mastectomy.

BRAC 1

A gene on chromosome 17 that normally helps to suppress cell growth. A person who inherits an altered version of the BRAC 1 gene has a higher risk of getting breast and ovarian cancer.

BRCA 2:

A gene that normally acts to restrain the growth of cells in the breast and ovary but which, when mutated, may predispose to breast cancer and to ovarian cancer.

Breast cancer in situ

Abnormal cells that are confined to the ducts or lobules in the breast. There are two forms, ductal carcinoma in situ (DCIS) and lobular carcinoma in situ (LCIS)

Breast density

Describes the relative amount of different tissue present in the breast. A dense breast has less fat than glandular and connective tissue. Mammogram films of breasts with higher density are harder to read and interpret than those of less dense breasts.

Breast implant

A silicone gel-filled or saline-filled sac placed under the chest muscle to restore breast shape.

Breast reconstruction

Surgery to rebuild the shape of the breast after a mastectomy.

Breast self-exam

An exam by a woman of her breast to check for lumps or other changes.

Breast conserving surgery and Breast-sparing surgery

An operation to remove the breast cancer but not the breast itself. Types of breast- conserving surgery include lumpectomy (removal of a lump), quadrantectomy (removal of one quarter, or quadrant of the breast), and segmental mastectomy (removal of the cancer as well as some of the breast tissue around the tumor and the lining over the chest muscles below the tumor).

C

Calcification

Deposits of calcium in the tissue. Calcification in the breast can be seen on a mammogram, but cannot be detected by touch. There are two types of breast calcifications, macrocalcifications and microcalcification. Macrocalcifications are large deposits and are usually not related to cancer. Microcalcifications are specks of calcium that may be found in an area of rapidly dividing cells. Many microcalcifications clustered together may be a sign of cancer.

Carcinoma (KAR-sih-NOH-muh)

Cancer that begins in the skin or in tissues that line or cover internal organs

Carcinoma in situ (KAR-sih-NOH-muh in SYE-too)

Epithelial cancer that lies above the basement membrane and has not spread to nearby lymphatic blood vessels' deeper structures.

Cell

The individual unit that makes up the tissues of the body. All living things are made up of one or more cells.

Chemotherapy (kee-moh-THAYR-uh-pee)

Treatment with drugs that kill cancer cells.

Clinical Breast exam

An exam of the breast performed by a health care provider to check for lumps or other changes.

Clinical trial

A type of research study that tests how well new medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease. Also called a clinical study.

Complementary and alternative medicine (CAM)

Forms of treatment that are used in addition to (complementary) or instead of (alternative) standard treatments. These practices generally are not considered standard medical approaches. Standard treatments go through long and careful research process to prove they are safe and effective, but less is known about most types of CAM. CAM may include dietary supplements, megadose vitamins, herbal preparations, special teas, acupuncture, message therapy, magnet therapy, spiritual healing, and meditation.

Core biopsy

The removal of a tissue sample with a large (typically 11 - 18 gauge) needle for examination under a microscope.

Cyst (sist)

A sac or capsule in the body. It may be filled with fluid or other materials.

D

Diagnosis

The process of identifying a disease by the signs and symptoms.

Diagnostic mammogram

X-ray of the breast to check for breast cancer after a lump or other sign or symptom of breast cancer has been found.

Digital mammography

A technique that uses a computer, rather than x-ray film, to record images of the breast.

Ductal carcinoma

The most common type of breast cancer. It begins in the cells that line the milk ducts in the breast.

Ductal carcinoma in situ (DCIS) (DUK-tal KAR-sih-NOH-muh-in- YE-too)

DCIS. A noninvasive, precancerous condition in which abnormal cells are found in the lining of a breast duct. The abnormal cells have not spread outside the duct to the tissues in the breast. In some cases, ductal carcinoma in situ may become invasive cancer and spread to other tissues, although it is not known at this time how to predict which lesions will become invasive. Also called intraductal carcinoma.

Ductal lavage (DUK-tal luh-VAHZ)

A method used to collect cells from milk ducts in the breast. A hair-size catheter (tube) is inserted into the nipple, and a small amount of salt water is released into the duct. The water picks up breast cells, and is removed. The cells are checked under a microscope. Ductal lavage may be used in addition to clinical breast examination and mammography to detect breast cancer.

Dysplasia (dis-PLAY-zha)

Cells that look abnormal under a microscope but are not cancer.

E**Estrogen (ES-TRUH-jin)**

A type of hormone made by the body that helps develop and maintain female sex characteristics and the growth of long bones. Estrogen can also be made in the laboratory. They may be used as a type of birth control and to treat symptoms of menopause, menstrual disorder, osteoporosis, and other disorders.

Estrogen receptor (ES-TRUH-jin re-CEP-tor)

A protein found inside the cells of the female reproductive tissue, some other types of tissue, and some cancer cells. The hormone estrogen will bind to the receptors inside the cells and may cause the cells to grow.

F**Fibroadenoma**

A noncancerous rubbery lump in the breast that is painless and moves around easily when touched.

Fibrocystic breast changes (FY-broh-SISS-tik) and Fibrocystic breast disease

A common condition marked by benign (noncancerous) changes in breast tissue. These changes may include irregular lumps or cysts, breast discomfort, sensitive nipples, and itching. These symptoms may change throughout the menstrual cycles and usually stop after menopause. Also called benign breast disease, fibrocystic breast changes and mammary dysplasia.

Fine-needle aspiration (as-per-AY-shun)

The removal of tissue or fluid with a needle for examination under a microscope. Also call needle biopsy.

G**Gene**

The functional and physical unit of heredity passed from parent to offspring. Genes are pieces of DNA and most genes contain the information for making a specific protein.

Gland

An organ that makes one or more substances, such as hormones, digestive juices, sweat, tears, saliva, or milk. Endocrine glands release the substances directly into a duct or opening inside or outside the body.

H

HER2/neu

Human epidermal growth factor receptor 2. The HER/neu (or C-erb B-2) (protein is involved in the growth of some cancer cells.

HER2/neu gene

The gene that makes the human epidermal growth factor receptor 2. The protein produced is HER2/neu, which is involved in the growth of some cancer cells. Also called c-erbB-2.

Hormone

A chemical made by glands in the body. Hormones circulate in the bloodstream and control the actions of certain cells or organs. Some hormones can also be made in a laboratory.

Hormone receptor

A protein on the surface of a cell that binds to a specific hormone. The hormone causes many changes to take place in the cell.

Hormone replacement therapy

HRT. Hormones (estrogen, progesterone, or both) given to women after menopause to replace the hormones no longer produced by the ovaries. Also called menopausal hormone therapy.

Hormone therapy

Treatment that adds, blocks, or removes hormones. For certain conditions (such as diabetes or menopause), hormones are given to adjust low hormone levels. To slow or stop the growth of certain cancers (such as prostate and breast cancer), synthetic hormones or other drugs may be given to block the body's natural hormones. Sometimes surgery is needed to remove the gland that makes a certain hormone. Also called hormonal therapy, hormone therapy, or endocrine therapy.

I

Immunotherapy (IH-myoo-noh-THAYR-uh-pee)

Treatment to stimulate or restore the ability of the immune system to fight cancer, infections and other diseases. Also used to lessen certain side effects that may be caused by cancer treatment. Also called biological therapy, biotherapy, or biological response modifier (BRM) therapy.

Incidence

The number of new cases of a disease diagnosed each year.

Incisional biopsy (in-SIH-zhun-al BY-op-see)

A surgical procedure in which a portion of a lump or suspicious area is removed for diagnosis. The tissue is then examined under a microscope.

Intraductal carcinoma (IN-truh-DUK-tul KAR-sih-NOH-muh)

A noninvasive, precancerous condition in which abnormal cells are found in the lining of a breast duct. The abnormal cells have not spread outside the duct to other tissues in the breast. In some cases, intraductal carcinoma may become invasive cancer and spread to other tissues, although it is not known at this time how to predict which lesions become invasive. Also called ductal carcinoma in situ.

Invasive cancer

Cancer that has spread beyond the layer of tissue in which it developed and is growing into surrounding, healthy tissues. Also called infiltrating cancer.

L**LCIS**

Lobular carcinoma in situ. Abnormal cells found in the lobules of the breast. The condition is considered nonmalignant; however, having lobular carcinoma in situ increases one's risk of developing breast cancer in either breast.

Lobe

A portion of an organ, such as the liver, lungs, breast, thyroid, or brain.

Lobular carcinoma

Cancer that begins in the lobules (the glands that make milk) of the breast. Lobular carcinoma in situ (LCIS) is a condition in which abnormal cells are found only in the lobules. When cancer has spread from the lobules to surrounding tissues, it is called invasive lobular carcinoma. LCIS in one breast increases the risk of developing invasive cancer in either breast.

Lymph node (limf node)

A rounded mass of lymphatic tissue that is surrounded by a capsule of connective tissue. Lymph nodes filter lymph (lymphatic fluid), and they store lymphocytes (white blood cells).

Lymph node mapping

The use of dyes and radioactive substances to identify lymph nodes that may contain tumor cells. Also called lymphatic mapping.

Lymphedema (LIMF-eh-DEE-ma)

A condition in which excess fluid collects in tissue and causes swelling. It may occur in the arm or leg after lymph vessels or lymph nodes in the underarm or groin are removed or treated with radiation.

M

Magnetic resonance imaging (mag-NET-ik REZ-o-nans IM-a-jing)

MRI. A procedure in which radio waves and a powerful magnet linked to a computer are used to create detailed pictures of areas inside the body. The pictures can show the difference between normal and diseased tissue. MRI makes better images of organs and soft tissue than other scanning techniques, such as CT or x-ray. MRI is especially useful for imaging the brain, spine, the soft tissue of joints, and inside bones. Also called nuclear magnetic resonance imaging.

Malignant (ma-LIG-nant)

Cancerous. Malignant tumors can invade and destroy nearby tissue and spread to other parts of the body.

Mammogram (MAM-o-gram)

An x-ray of the breast.

Mammography (mam-OG-ra-fee)

The use of x-rays to create a picture of the breast.

Margin

The edge or border of the tissue removed in cancer surgery. The margin is described as negative or clean when the pathologist finds no cancer cells at the edge of the tissue, suggesting that all the cancer has been removed. The margin is described as positive or involved when the pathologist finds cancer cells at the edge of the tissue, suggesting that all of the cancer has not been removed.

Mastectomy (mas-TEK-toe-mee)

Surgery to remove the breast (or as much of the breast tissue as possible).

Menarche

A young woman's first menstrual period.

Menopause (MEN-uh-pawz)

The time of life when a woman's menstrual periods stop. A woman is in menopause when she hasn't had a period for 12 months in a row. Also called "change of life."

Metastasis (meh-TAS-ta-sis)

The spread of cancer from one part of the body to another. A tumor formed by cells that have spread is called a "metastatic tumor" or a "metastasis." The metastatic tumor contains cells that are like those in the original (primary) tumor. The plural form of metastasis is metastases (meh-TAS-ta-seez).

Microcalcification (MY-krow-kal-si-fi-KAY-shun)

A tiny deposit of calcium in the breast that cannot be felt but can be detected on a mammogram. A cluster of these very small specks of calcium may indicate that cancer is present.

N**Needle biopsy**

The removal of tissue or fluid with a needle for examination under a microscope. Also called fine-needle aspiration.

Needle-localized biopsy

A procedure that uses very thin needles or guide wires to mark the location of an abnormal area of tissue so that it can be surgically removed. An imaging device is used to place the wire in or around the abnormal area. Needle localization is used when the doctor cannot feel the mass of abnormal tissue.

Neoadjuvant therapy (NEE-o-AD-joo-vant)

Treatment given before the primary treatment. Examples of neoadjuvant therapy includes chemotherapy, radiation therapy, and hormone therapy.

Nipple discharge

Fluid coming from the nipple.

Nonmalignant

Not cancerous.

O**Oncologist (on-KOL-o-jist)**

A doctor who specializes in treating cancer. Some oncologists specialize in a particular type of cancer treatment. For example, a radiation oncologist specializes in treating cancer with radiation.

Oncology

A study of cancer.

P**Palpation**

Examination by pressing on the surface of the body to feel the organs or tissues underneath.

Pathologist (pa-THOL-o-jist)

A doctor who identifies diseases by studying cells and tissues under a microscope.

Pathology report

The description of cells and tissues made by a pathologist based on microscopic evidence, and sometimes used to make a diagnosis of a disease.

Prevention

In medicine, action taken to decrease the chances of getting a disease. For example, cancer prevention includes avoiding risk factors (such as smoking, obesity, lack of exercise, and radiation exposure) and increasing protective factors (such as getting regular physical activity, staying at a healthy weight, and eating a healthy diet).

Progesterone (pro-JES-tuh-rone)

A female hormone.

Progesterone receptor (PR)

A protein found inside the cells of the female reproductive tissue, some other types of tissue, and some cancer cells. The hormone progesterone will bind to receptors inside the cells and may cause the cells to grow.

Prognosis (prog-NO-sis)

The likely outcome or course of a disease; the chance of recovery or recurrence.

Prophylactic mastectomy (PROH-fuh-LAK-tik ma-STEK-tuh-mee)

Surgery to reduce the risk of developing breast cancer by removing one or both breasts before disease develops. Also called a preventive mastectomy.

Prosthesis (pros-THEE-sis)

A device that replaces a body part.

Punctate – Having small pin point calcium deposits.**R****Radiation (ray-dee-AY-shun)**

Energy released in the form of particles or electromagnetic waves. Common sources of radiation include radon gas, cosmic rays from outer space, and medical x-rays.

Radiation oncologist (ray-dee-AY-shun on-KOL-o-jist)

A doctor who specializes in using radiation to treat cancer.

Radiation therapy

The use of high-energy radiation from x-rays, gamma rays, neutrons and other sources to kill cancer cells and shrink tumors. Radiation may come from a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy, implant radiation, or brachytherapy). Systemic radiation therapy uses a radioactive substance, such as radiolabeled monoclonal antibody, that circulates throughout the body. Also called radiotherapy.

Radical mastectomy (RAD-ih-kul mas-TEK-toe-mee)

Surgery for breast cancer in which the breast, chest muscles, and all of the lymph nodes under the arm are removed. For many years, this was the breast cancer operation used most often, but it is used rarely now. Doctors consider radical mastectomy only when the tumor has spread to the chest muscles. Also called the Halsted radical mastectomy.

Radiologist (RAY-dee-OL-o-jist)

A doctor who specializes in creating and interpreting pictures of areas inside the body. The pictures are produced with x-rays, sound waves, or other types of energy.

Reconstructive surgeon

A doctor who can surgically reshape or rebuild (reconstruct) a part of the body, such as a woman's breast after surgery for breast cancer.

Recurrence

Cancer that has returned after a period of time during which the cancer could not be detected. The cancer may come back to the same place as the original (primary) tumor or to another place in the body. Also called recurrent cancer.

Remission

A decrease in or disappearance of signs and symptoms of cancer. In partial remission, some, but not all, signs and symptoms of cancer have disappeared. In complete remission, all signs and symptoms of cancer have disappeared, although cancer still may be in the body.

Risk factor

Something that may increase the chance of developing a disease. Some examples of risk factors for cancer include age, a family history of certain cancers, use of tobacco products, certain eating habits, obesity, lack of exercise, exposure to radiation or other cancer-causing agents, and certain genetic changes.

S

Scintimammography

A type of breast imaging test that is used to detect cancer cells in the breasts of some women

who have had abnormal mammograms, or who have dense breast tissue. Scintimammography is not used for screening, or in place of a mammogram. In this test, a woman receives an injection of a small amount of a radioactive substance called technetium 99, which is taken up by the cancer cells, and a gamma camera is used to take pictures of the breasts.

Screening

Checking for disease when there are no symptoms.

Screening mammogram

An x-ray of the breast used to detect breast changes in women who have no signs of breast cancer.

Sentinel lymph node mapping

The use of dyes and radioactive substances to identify the first lymph node to which cancer is likely to spread from a primary tumor. Cancer cells may appear first in the sentinel node before spreading to other lymph nodes and other places in the body.

Sonogram (SON-o-gram)

A computer picture of areas inside the body created by bouncing high-energy sound waves (ultrasound) off internal tissues or organs. Also called an ultrasonogram.

Stage

The extent of a cancer in the body. Staging is usually based on the size of the tumor, whether lymph nodes contain cancer, and whether the cancer has spread from the original site or other parts of the body.

Stage II breast cancer

Stage II is divided into Stage IIA and IIB based on the tumor size and whether it has spread to the axillary lymph nodes (the lymph nodes under the arm). In Stage IIA, the cancer is either no larger than 2 centimeters and has spread to the axillary lymph nodes, or between 2 and 5 centimeters but has not spread to the axillary lymph nodes. In Stage IIB, the cancer is either between 2 and 5 centimeters and has spread to the axillary lymph nodes, or larger than 5 centimeters and has spread to the axillary lymph nodes, or larger than 5 centimeters but has not spread to the axillary lymph nodes.

Stage III breast cancer

Stage III is divided into stages IIIA, IIIB and IIIC. In Stage IIIA breast cancer, the cancer (1) is smaller than 5 centimeters (2 inches) and has spread to the lymph nodes in the armpit, which have grown into each other or into other structures and are attached to them; or (2) is larger than 5 centimeters and has spread to the lymph nodes in the armpit. In Stage IIIB breast cancer, the cancer (1) has spread to tissues near the breast (skin, chest wall, including the ribs and the muscles in the chest) or (2) has spread to lymph nodes inside the chest wall along the breast bone.

In Stage IIIC, cancer has spread to the lymph nodes beneath the collarbone and near the neck; may have spread to lymph nodes within the breast or under the arm and to tissues near the breast.

Stage IV breast cancer

Cancer has spread to other organs of the body, most often the bones, lungs, liver, or brain.

Stem cell

A cell from which other types of cells develop. Blood cells develop from blood-forming stem cells.

Stereotactic biopsy (STAYR-ee-io-TAK-tik BY-op-see)

A biopsy procedure that uses a computer and a 3-dimensional scanning device to find a tumor site and guide the removal of tissue for examination under a microscope.

Surgical oncologist

A doctor who performs biopsies and other surgical procedures in cancer patients.

T

Tamoxifen (ta-mok-si-FEN)

A drug used to treat breast cancer, and to prevent it in women who are at high risk of developing breast cancer. Tamoxifen blocks the effects of the hormone estrogen in the breast. It belongs to the family of drugs called antiestrogens.

Tissue flap reconstruction

A type of breast reconstruction in which a flap of tissue is surgically moved from another area of the body to the chest, and formed into a new breast mound.

Tumor

An abnormal mass of tissue that results when cells divide more than they should or do not die when they should. Tumors may be benign (non-cancerous) or malignant (cancerous). Also called neoplasm.

Tumor grade

The degree of abnormality of cancer cells, a measure of differentiation. The extent to which cancer cells are similar in appearance and function to healthy cells of the same tissue type. The degree of differentiation often relates to the clinical behavior of the particular tumor. Based on the microscopic appearance of cancer cells, pathologists commonly describe tumor grade by four degrees of severity: Grades 1, 2, 3, and 4 (1 low grade ... 4 high grade).

U

Ultrasound

A procedure in which high-energy sound waves (ultrasound) are bounced off internal tissue or organs and make echoes. The echo patterns are shown on the screen of an ultrasound machine, forming a picture of the body tissues called a sonogram. Also called ultrasonography.

X

X-ray

A type of high-energy radiation. In low doses, x-rays are used to diagnose diseases by making pictures of the inside of the body. In high doses, x-rays are used to treat cancer. No longer widely available.

National Cancer Institute. Dictionary of Cancer Terms. Retrieved on October 20-21, 2005 from <http://www.cancer.gov/dictionary/>.

N.C. BCCCP Eligibility and Other Funding Resources

NORTH CAROLINA BCCCP-ELIGIBLE POPULATION

- A. Women 40-64 years of age with gross incomes that are <250% of the federal poverty level, according to the Federal Poverty Guidelines, and who are uninsured or underinsured, may be eligible for breast services, subject to the limitations and exceptions listed below.
- B. Women enrolled in Medicare (Part B) and/or Medicaid programs are not eligible for program-funded services.
- C. Women receiving Family Planning (Title X) services are not eligible for NC BCCCP-funded services that are available through Title X funding.
- D. The priority population for National Breast and Cervical Cancer Early Detection Program (NBCCEDP) mammography services consists of women between the ages of 50 and 64 who are low-income (250% of federal poverty level or less), who have not been screened in the past year. Women with normal screening results may be screened every 1 to 2 years.
- E. Income eligibility must be reassessed annually based on the revised federal poverty level. The current federal poverty guidelines are on the following page.
- F. Priority populations also include women of ethnic minorities and those who are uninsured or underinsured.
- G. Eligible women 18-39 with an undiagnosed breast or cervical abnormality may be able to receive NC BCCCP-funded diagnostic services if no other source of health care reimbursement is available.
- H. At least 75% of the women provided mammograms must be between the ages of 50 and 64.
- I. Women enrolled in NC BCCCP with biopsy-proven diagnoses of pre-cancer or cancerous conditions are eligible for Breast and Cervical Medicaid (BCCM). To be eligible women must be enrolled in the NC BCCCP before receiving a biopsy-proven diagnosis. This funding is short term, for aggressive treatment. Appendix II provides additional information about NCBCCCP and BCCM.

Cancer Prevention and Control Branch

Federal Poverty Guidelines

Fiscal year 2006-2007

Persons in Family Unit	48 states + D.C.	250% FPG (Annual)	250% FPG (Monthly)	115% FPG (Annual)
1	\$9,800	\$24,500	\$2,042	\$11,270.00
2	\$13,000	\$33,000	\$2,750	\$15,180.00
3	\$16,600	\$41,500	\$3,458	\$19,090.00
4	\$20,000	\$50,000	\$4,167	\$23,000.00
5	\$23,400	\$58,500	\$4,875	\$26,910.00
6	\$26,800	\$67,000	\$5,583	\$39,820.00
7	\$30,200	\$75,500	\$6,292	\$34,730.00
8	\$33,600	\$84,000	\$7,000	\$38,640.00
for each additional person, add	\$3,400	\$8,499	\$2,458	

**Source: Federal Register, Vol. 71, No. 15, January 24, 2006*

NCBCCCP Program Description



Program Goal

- Reduce mortality and morbidity of breast and cervical cancers in North Carolina Women.

Program Objectives

- Increase the screening and follow-up of breast and cervical cancers
- Improve the screening knowledge, attitudes and practices regarding breast and cervical cancers
- Improve the screening clinical detection practices for breast and cervical cancers
- Ensure optimal screening and follow-up procedures
- Ensure appropriate medical treatment referral and support services
- Monitor the distribution and determinants of the incidence and mortality of breast and cervical cancers

Program Services and Activities

Screening and Follow-up: Eligible NCBCCCP clients may receive screening mammogram, clinical breast exam, pelvic exam, Pap smear, and/or diagnostic mammogram, fine needle aspiration, breast ultrasound, needle core biopsy, colposcopy, colposcopy-directed biopsy and follow-up referral as needed.

Case Management: Includes ensuring appropriate referrals for medical treatment and providing appropriate follow-up and support services for NCBCCCP clients.

Professional Education: Includes clinical education and program updates for health care providers and other health care professionals.

Public Education/Communications: Includes education to increase public awareness and local community outreach strategies via community building, multichannel marketing and media campaigns, lay health advisors and printed materials.

Quality Assurance: Includes consultation/technical assistance, review and update of clinical protocols, and monitoring of adherence to accreditation and certification standards.

Surveillance and Evaluation: Includes epidemiological surveillance, monitoring of data management, and evaluation of program operations and procedures.

Breast and Cervical Cancer Medicaid (BCCM): Women who are enrolled and who have breast or cervical cancer diagnosed through the Program are eligible to apply for Breast and Cervical Cancer Medicaid to cover their cancer treatment costs.

Program Eligibility

Women who are at or below 250% of the Federal Poverty Guidelines, are uninsured or underinsured, and do not have Medicare Part B or Medicaid.

- Special emphasis is placed on recruiting ethnic minority women ages 50-64.

Program Service Locations

Administered locally through NCBCCCP-contracted providers.

Local Program Information

Contact North Carolina Breast and Cervical Cancer Control Program • (919) 707-5300

Make early detection a habit for life!

Breast and Cervical Cancer Medicaid (BCCM)



History of Breast and Cervical Cancer Medicaid (BCCM)

October 2002 Breast and Cervical Cancer Prevention and Treatment Act (106-354) enacted for eligible National Breast and Cervical Early Detection Program (NBCCEDP) patients.

January 2002 Eligible Clients of NCBCCCCP begin to receive Breast and Cervical Cancer Medicaid for surgical intervention and other treatment of diagnosed breast and cervical cancers.

Do you have patients or do you know women who are eligible for and would benefit from Medicaid paying for their breast and cervical cancer treatment?

Patients must be referred to the local NCBCCCCP prior to diagnosis to be eligible for Breast and Cervical Medicaid.

Be an advocate for women to receive needed intervention for breast and cervical cancers!

Women must be eligible for NCBCCCCP . . .

Eligibility includes –

- Women who are at or below 250% of the Federal Poverty Guidelines, are uninsured or under insured, and are not covered by Medicare Part B.
- Preference is given to women ages 50-64 and ethnic minorities do to the greater incidence of and/or mortality from these cancers.

Physicians Beware: Diagnosis of the cancer must NOT be made prior to your patient becoming a NCBCCCCP client. Prior diagnosis will result in patient ineligibility.

Enroll an eligible patient in NCBCCCCP by . . .

- Referral to local NCBCCCCP when there is an abnormal screening or diagnostic test result, but before cancer is diagnosed.
- Provide preliminary screening test (CBD, screening and/or diagnostic mammogram, Pap test, colposcopy, etc.) with referral.

Final diagnostic testing will be done through NCBCCCCP with NCBCCCCP funds.

Diagnosis made to eligible women through NCBCCCCP open the door to Medicaid eligibility. Application for BCCCM us made through local NCBCCCCP provider

For more information, contact the North Carolina Breast and Cervical Cancer Program at 919-707-5300.

Rev/4/06

Cancer Assistance Unit

The Cancer Assistance Unit

We're here for you!

What is Cancer Assistance?

The **Cancer Assistance Unit** (it used to be the Cancer Control Program) is a part of the North Carolina Comprehensive Cancer Program. You can get information on cancer-related resources, services, and financial assistance.

What kind of financial assistance might I get?

Cancer Assistance covers payment of medical care for eligible persons who need services for cancer diagnosis or cancer treatment. It can cover inpatient, outpatient, or the office/clinic.

How do I qualify?

To qualify for Cancer Assistance you must meet three requirements.

1. Residency

- U.S. citizen and a permanent resident of North Carolina, or
- A migrant farm worker or the dependent of one
- INS documentation is required if you have applied for U.S. citizenship or a permanent resident visa.

2. Financial

- Income is based must be at or above 115% of the federal poverty level
- Not eligible for Medicaid and have little or no health insurance

3. Medical

- Have symptoms or conditions that indicate cancer or be diagnosed as having cancer
- Have an estimated 25%, or better, chance of 5-year survival at the time of treatment

What does Cancer Assistance pay for?

- Diagnostic services for up to 8 days for each fiscal year (July 1 to June 30)
- Treatment services for up to 30 days for each fiscal year (July 1 to June 30)
- Follow-up services may be covered for up to 2 days for diagnostic services if they fall within the 8 diagnostic service days or within 30 treatment days that are allowed.
- Coverage usually includes doctor services in both inpatient (hospital) and outpatient as well as clinic or office
- Payment is paid directly to the medical care provider or health care facility

What is not covered?

Cancer Assistance does not cover:

- Treatments or efforts that lessen pain, side-effects, or other discomforts (palliative procedures)
- Drugs or medicines used outside the treatment facility
- Cost of travel to and from diagnosis or treatment



At the North Carolina Comprehensive Cancer Program, your health matters to us.

Financial Eligibility Income Scales

(Based on 115% of the federal poverty scale)

Family Size	1 July 2005 - 30 June 2006 Family GROSS Income	1 July 2006 - 30 June 2007 Family GROSS Income
1	\$11,006	\$11,270
2	\$14,755	\$15,180
3	\$18,504	\$19,090
4	\$22,253	\$23,000
5	\$26,002	\$26,910
6	\$29,751	\$30,820
7	\$33,500	\$34,730
8	\$37,249	\$38,640
	Add \$3,749 for each additional person	Add \$3,910 for each additional person

Sources for More Information:

North Carolina

Comprehensive Cancer Program

Division of Public Health

1922 Mail Service Center

Raleigh, North Carolina 27699-1922

Phone: (919) 707-5321

Fax: (919) 870- 4812

Patient Line (Toll Free): 1-866-693-2656

www.nccancer.org

(Questions, medical eligibility, program manual)

Cancer Information Line

1-800-227-2345 (24-hour line)

www.cancer.org

Cancer Information Service

National Cancer Institute

1-800-4-CANCER

(1-800-422-6237)

www.cancer.gov

(To learn more about cancer)

Purchase of Medical Care Services

1904 Mail Service Center

Raleigh, North Carolina 27699-1904

Phone: (919) 855-3701 *(Eligibility)*

(919) 855-3672 *(To order forms)*

Fax: (919) 715-3848

CARE-LINE

Information and Referral Service

(English/Espanol)

1-800-662-7030

(919) 855-4400

*Provides information and referral on human services
provided by government and nonprofit agencies*

Funding Resources Outside of NCBCCCP

Below is information on various organizations that may assist women who do not qualify for our program or for our Medicaid Treatment Act:

1. The Patient Advocate Foundation (PAF) has case managers who can guide the client through her treatment process. To qualify for assistance with the PAF, the enrollee needs to meet income eligibility requirements, have a physician certify that the client's condition is such that she will be out of work for 12 months or more, and provide documentation including history, physical exam, operative reports, etc. Please contact PAF at their toll-free number: 1-800-532-5274 to obtain specific information related to your situation.
2. The AstraZeneca Foundation Patient Assistance Program provides therapies free of charge to those who could not otherwise afford them. Contact the AstraZeneca Cancer Support Network at 1-866-99 AZ CSN or 1-866-922-9276 Monday through Friday, 9:00 am – 7:00 PM ET, excluding holidays, to obtain information and resources based on your situation.
3. Two other drug assistance programs can be found under the web site www.TogetherRxAccess.com and under www.us.femara.com (800-282-7630).
4. Contact the NC Women's and Children's Health Section to find out if the patient qualifies for the medically needy program. Telephone Number: (919) 707-5510.
5. Office of Eligibility Determination is where to find out if patients qualify for contact information p m straight Medicaid or not.
6. Harvest of Hope Foundation - 888-922-4673 - monies for health care costs
7. There is an Avon Foundation-funded program called the AVONCares Program at Cancer Care, which provides funds for transportation to and from treatment once an individual is diagnosed with breast cancer. Please call 1-800-813-HOPE (4673) to speak with an oncology social worker, who can provide more information on this and other Cancer Care programs that may be of assistance.
8. Merck & Co., Inc. has a drug assistance program. Visit www.merckuninsured.com , or call 1-800-50-MERCK for more information about the program and enrollment forms.
9. The Susan B. Komen Breast Cancer Foundation, www.komen.org. 1-800-I'm Aware® (1-800-462-9273).
10. CancerCare Assist®
www.cancercare.org/get_help/assistance/cc_financial.php

Dose to Staff Who Restrain Patients During Mammographic Procedures

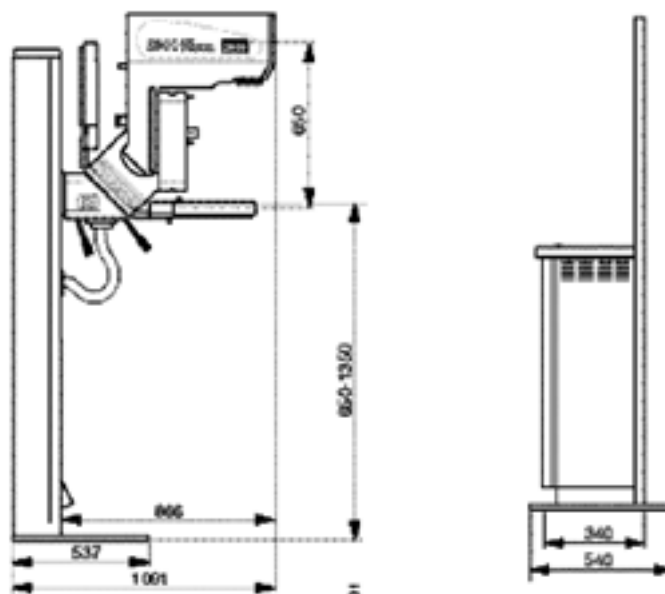
Robert Reiman, MD
Duke University Medical Center
3 Feb 2006

PURPOSE: To evaluate radiation dose to ancillary staff who must restrain patients during mammographic procedures using a Siemens Mammomat 3000 mammography unit.

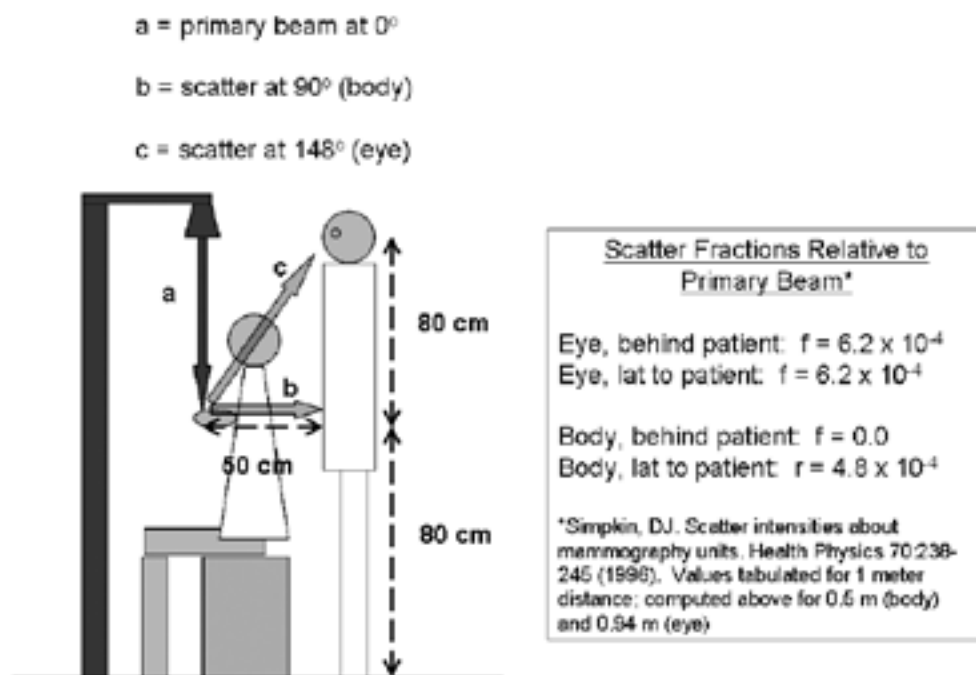
METHOD: The scatter dose distribution around a Mammomat 3000 unit is not available. However, the important parameters determining exposure to staff depend upon technical factors (kVp, mAs, and beam quality) that are more or less independent of the particular model of x-ray machine. Furthermore, uncertainties in parameters such as breast thickness and position of staff during procedures permit only a very approximate estimation of dose.

Determination of entrance air kerma: Values of air kerma ($\mu\text{Gy}/\text{mAs}$) at the breast surface as a function of kVp are taken from Robson 2001. The curve for 25 micron molybdenum filter and 1 mm Perspex compression plate gives the largest (most conservative) values for air kerma. At 27 kVp, the air kerma is $98.5 \mu\text{Gy}/\text{mAs}$. For a mAs of 67.2, the entrance air kerma is 6.6 mGy, corresponding to an entrance exposure of about 0.76 R. This is approximately the exposures encountered in practice for an average-size breast (4 cm thick on compression). This value will be used as the source term for scatter calculations at various distances and angles.

Location of Staff During Exposures: The layout of the Mammomat 3000 unit and its chair are shown in the figures below. The dimensions are in units of millimeters.



Based on these dimensions, an idealized geometry showing the relative positions of x-ray beam, patient and staff (in Position A, behind chair) is shown in the figure below (not to scale).



In Position B, the staff member is lateral to the patient. The staff member is assumed to be 170 cm tall (ICRP 23 Reference Man) with eye level at 160 cm. The patient's breast is assumed to be 80 cm from the floor and 50 cm from the anterior surface of the staff member. The distance of the staff member's eye to the patient's breast is computed to be 0.94 meters at an angle of 148 degrees based on the above geometry. Values for the scatter fraction at one meter are taken from Simpkin 1996. The scatter fractions at 0.94 meter and 0.50 meter are computed based on inverse square law. The values of air kerma (dose) at the eye and the abdomen of the staff member at Positions A and B are shown in the table below. Values assume the above air kerma source term and four films per procedure.

Staff Member Position	Eye Dose	Body Surface Dose (no lead PPE)	Body Surface Dose (0.25 mm lead PPE)
A (Behind Patient)	0.016 mGy	0.0 mGy	0.0
B (Lateral to Patient)	0.016 mGy	0.013 mGy	0.0

CONCLUSIONS: Both the dose to the lens of the eye and the body surface dose incurred by a staff member during a four-film mammography procedure are very low and carry no health risks, even if shielding PPE is not employed. By way of comparison, the radiation dose accumulated by an airline passenger during a flight from New York to Los Angeles is about 0.05 mGy.

If the staff member is positioned behind the patient (Position A), then the body dose is nearly zero due to the low energy scattered photons being absorbed by the patient's body. Position A would be the recommended position for standing while restraining the patient. Body exposure would be reduced to zero if appropriate shielding PPE ("lead apron") were to be worn by the staff member during exposures.

Although these radiation doses are very low on a per-procedure basis, the following steps to minimize radiation dose to ancillary staff are appropriate:

- a) Mechanical restraint should be employed whenever practical;
- b) If human holders must be used, they must wear shielding PPE that covers the anterior surface of the body with at least 0.25 mm lead equivalent during exposures, pursuant to 15 NCAC11 Section .0603(a)(1)(E)(ii);
- c) Holders shall not place their hands in the primary (useful) x-ray beam unless the hands are protected by 0.5 mm lead equivalent, pursuant to 15 NCAC11 Section 603(a)(1)(E)(i);
- d) No individual shall be primarily employed as a "holder." pursuant to 15 NCAC11 Section 0603(a)(1)(H)(iv). Individuals should be rotated in and out of "holding" responsibilities.

DISCLAIMER: These dose estimates are for informational purposes only, and are not to be used for purposes of regulatory compliance. Regulatory compliance should be demonstrated by consultation with qualified experts in x-ray shielding design. Calculations are valid only under the conditions described above. Duke University Medical Center makes no warranty as to the suitability of this evaluation for any other purpose.

REFERENCES:

Robson, KJ. A parametric method for determining mammographic x-ray tube output and half-value layer. *Brit J Radiol* 74: 335-340 (2001)

Simpkin DJ. Scatter intensities about mammography units. *Health Physics* 70:238-245 (1996).

Reprinted with the permission of Robert Reiman, MD, Duke University Medical Center, 02/03/2006

Breast Cancer Staging

Women who are diagnosed with breast cancer will be assigned a stage of disease by the specialist who makes the diagnosis. Although it will not be necessary for providers in local health departments to assign a stage to a patient's cancer, understanding the staging system might be helpful in interpreting correspondence from oncologists or breast surgeons.

The TNM classification describes the extent of the patient's primary tumor, any metastases to lymph nodes, and any distant metastases. Some physicians will stage the T, the N and the M, and the results are the group stage with the Roman numerals. Providers who want more information on the staging system can refer to the article in the following pages or the website for the American Joint Committee on Cancer at <http://www.cancerstaging.org/products/ajccproducts.html>.

TNM classification¹

Primary tumor (T)

TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma in situ (includes Paget's disease of the nipple with no apparent tumor)
T1	Tumor ≤ 2 cm in greatest dimension
T2	Tumor >2 cm but ≤5cm in greatest dimension
T3	Tumor >5 cm in greatest dimension
T4	Tumor of any size with direct extension to chest wall or skin

Regional lymph nodes (N)

NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastases
N1	Metastasis in movable ipsilateral axillary lymph node(s)
N2	Metastases in ipsilateral axillary lymph nodes fixed or matted, or in clinically apparent ipsilateral internal mammary nodes in the absence of clinically evident axillary lymph node metastasis
N3	Metastasis in ipsilateral infraclavicular lymph node(s), or in clinically apparent ipsilateral internal mammary node(s) and in the presence of clinically evident axillary lymph node metastasis; or metastasis in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph node involvement

Distant metastasis (M)

MX	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis.

Stage Groupings

Stage 0:	Tis,N0,M0
Stage I:	T1,N0,M0
Stage IIA:	T0,N1,M0; T1,N1,M0; T2,N0,M0
Stage IIB:	T2,N1,M0; T3,N0,M0
Stage IIIA:	T0,N2,M0; T1,N2,M0; T2,N2,M0; T3,N1,M0; T3,N2,M0
Stage IIIB:	T4,Any N,M0
Stage IIIC:	Any T,N3,M0
Stage IV:	Any T,Any N,M1

From Singletary SE, Connolly JL. Breast cancer staging: working with the sixth edition of the AJCC Cancer staging manual. CA Cancer J Clin 2006;56:37-47.

CA

A Cancer Journal for Clinicians

Breast Cancer Staging: Working With the Sixth Edition of the AJCC Cancer Staging Manual

S. Eva Singletary and James L. Connolly
CA Cancer J Clin 2006;56:37-47

This information is current as of August 8, 2006

The online version of this article, along with updated information and services, is located on the World Wide Web at:
<http://caonline.amcancersoc.org/cgi/content/full/56/1/37>

To subscribe to the print issue of *CA: A Cancer Journal for Clinicians*, go to (US individuals only): <http://caonline.amcancersoc.org/subscriptions/>

CA: A Cancer Journal for Clinicians is published six times per year for the American Cancer Society by Lippincott Williams & Wilkins. A bimonthly publication, it has been published continuously since November 1950. *CA* is owned, published, and trademarked by the American Cancer Society, 1599 Clifton Road, NE, Atlanta, Georgia 30329. (©American Cancer Society, Inc.) All rights reserved. Print ISSN: 0007-9235. Online ISSN: 1542-4863.



Breast Cancer Staging: Working With the Sixth Edition of the *AJCC Cancer Staging Manual*

S. Eva Singletary, MD, FACS; James L. Connolly, MD

ABSTRACT The sixth edition of the *AJCC Cancer Staging Manual* contains some of the most extensive and significant revisions that have ever been made in the breast cancer staging system. The principal changes are related to the size, number, location, and method of detection of regional metastases to the lymph nodes. Some changes are related to the growing use of new technology (eg, sentinel lymph node biopsy, immunohistochemical staining, reverse transcriptase-polymerase chain reaction), whereas others are amendments of prior staging criteria, reflecting recent clinical evidence or widespread clinical consensus. Available data did not support the addition of new prognostic indicators such as histologic tumor grade to the tumor-node-metastasis system at this time. Future developments in determining breast cancer prognosis will most likely incorporate new approaches to identifying the genetic fingerprint of individual tumors. (*CA Cancer J Clin* 2006;56:37-47.) © American Cancer Society, Inc., 2006.

INTRODUCTION

Until fairly recently, breast cancer was treated as a single deadly disease for which the most extreme treatments were justified. Egyptian physicians in 1600 B.C. recorded the use of cauterization to treat breast cancers, and extensive surgeries removing the breast and all the surrounding muscle and bone were used during the Renaissance period. A less extreme but still extensive surgery was later adapted by Halsted as the standard of care in the late 19th century.¹

By the first half of the 20th century, clinicians had become aware that not all breast cancers shared the same prognosis or required the same treatment, and attempts were made to define characteristics that could reliably distinguish those tumors that required aggressive treatment from those that did not. In 1904, the German physician Steintal² proposed the division of breast cancer into three prognostic stages: small tumors that appeared to be localized to the breast (Stage I), larger tumors that involved the axillary lymph nodes (Stage II), and tumors that had clearly invaded tissues around the breast (Stage III). This simple staging system was further refined by Greenough, who based his classifications on microscopic examination of breast cancer specimens.³ The four-stage Columbia Clinical Classification System for breast cancer, with Stages A through C corresponding to Steintal's stages, and Stage D representing disease that had metastasized throughout the body, was introduced in 1956 by Haagensen and Stout.

The tumor-node-metastasis (TNM) system was developed by Pierre Denoix starting in 1942 and represented an attempt to classify cancer based on the major morphological attributes of malignant tumors that were thought to influence disease prognosis: size of the primary tumor (T), presence and extent of regional lymph node involvement (N), and presence of distant metastases (M). The International Union Against Cancer (UICC) presented a clinical classification of breast cancer based on the TNM system in 1958,⁴ and the American Joint Committee on Cancer (AJCC) published a breast cancer staging system based on TNM in their first cancer staging manual in 1977.⁵ Since that time, regular revisions have been issued to reflect major advances in diagnosis and treatment. In the 1987 revision, differences between the AJCC and UICC versions of the TNM system were eliminated.

Dr. Singletary is Professor, Department of Surgical Oncology, University of Texas MD Anderson Cancer Center, Houston, TX.

Dr. Connolly is Director of Anatomic Pathology, Department of Pathology, Harvard Medical School/Beth Israel Deaconess Medical Center, Boston, MA.

This article is available online at <http://jcoonline.amcancer.org>

For the clinician, breast cancer staging is useful because of its ability to estimate prognosis. Figure 1 shows the relationship between cancer stage and 10-year relative survival in breast cancer patients, adapted from a report by Bland and colleagues⁶ that used data from 1.3 million cases (1985 to 1996) in the National Cancer Data Base (NCDB). There are significant differences among stages: only 5% to 12% of Stage I/II patients die in the first 10 years after diagnosis, compared with over 60% of Stage III patients and over 90% of Stage IV patients. Breast cancer staging also provides valuable information about appropriate treatment options for each cancer stage.⁶ Because AJCC/UICC staging is commonly used to select patients and to report outcomes in clinical trials, clinicians can make a reasoned judgment about whether treatment strategies reported in the literature will be appropriate for their patients.

Breast cancer staging provides useful information about the current status of cancer detection and management, and the success of implementing new strategies. For example, data from the NCDB show that the percentage of US patients initially presenting as Stage 0 or Stage I increased from 42.5% in 1985 to 56.2% in 1995, whereas the percentage of patients presenting as Stage III or Stage IV decreased from 18.3% to 11.6% during the same time period.⁶ This changing picture suggests that the increased usage of screening mammography during the same time period was effective in detecting cancer at an earlier stage when it can be more successfully treated.

In developing countries, staging of breast cancer patients can provide revealing epidemiological information about opportunities for improving breast cancer screening and management. In contrast to the NCDB data from US women shown above, studies of women with breast cancer from Tanzania,⁷ Tunisia,⁸ Nigeria,⁹ and South Africa¹⁰ have shown that most are initially seen when their cancers are very advanced (Stage III and IV). Public and private agencies interested in international public health programs can use such information to document need and to optimize their interventions.

In this article, we will review the recent revision of the AJCC staging system for breast cancer,¹¹ detailing the specific changes that were made and providing guidelines for using the system in daily practice. We will then review frequently asked questions about implementation of the revised staging system that have been submitted to the AJCC by clinicians from around the world. Finally, we will discuss the future of TNM staging in a world of rapidly developing new technology.

THE SIXTH EDITION OF THE AJCC CANCER STAGING MANUAL: NEW STAGING DIRECTIONS FOR BREAST CANCER

Why a Revision Was Needed

Since the fifth edition of the *AJCC Cancer Staging Manual* was published in 1997,¹² important developments have occurred in breast cancer diagnosis and management:

- Because of the increasing use of screening mammography, the average size of breast tumors when first detected has decreased significantly.¹³ Although many of these small tumors could be treated adequately with surgery alone, a significant percentage of these patients would benefit from adjuvant therapy.
- These smaller tumors are associated with a decreased probability of axillary lymph node metastases.¹⁴ Because of this, clinicians have moved away from the use of axillary lymph node dissection (with its associated morbidities) for assessing lymph nodes and have enthusiastically embraced the new technique of sentinel lymph node biopsy (SLNB). Some issues remain unresolved about the most appropriate candidates and methodology for SLNB.
- The growing use of immunohistochemical (IHC) staining and molecular biology techniques has led to concerns about the clinical significance of the extremely small metastatic lesions that can be detected by these approaches.
- The clinical importance of total number of positive axillary lymph nodes, now widely

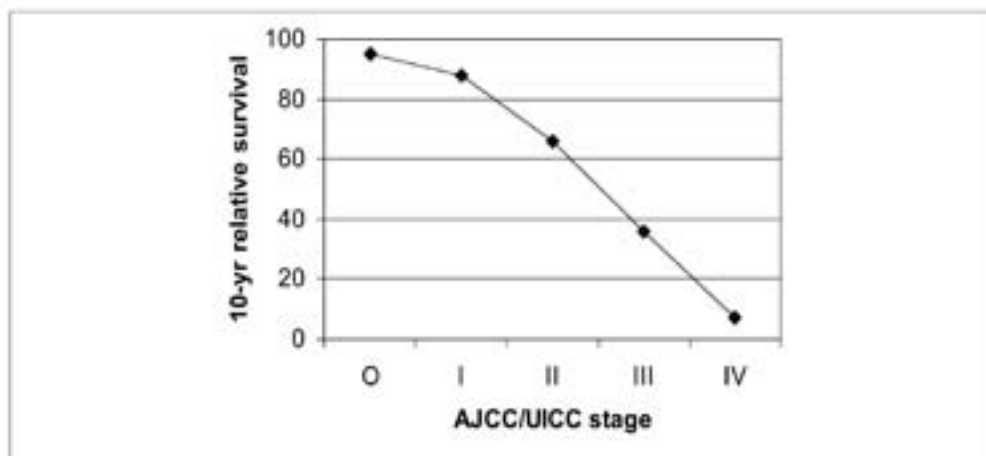


Figure 1 Ten-year Relative Survival Associated with AJCC/UICC (TNM) Breast Cancer Stage. Adapted from a report by Bland, et al.⁸ that used data from 1.3 million cases (1985 to 1996) in the National Cancer Data Base.

recognized by clinicians, has not previously been reflected in breast cancer staging.

- New information about clinical outcomes associated with metastases to supraclavicular, infraclavicular, and internal mammary lymph nodes has led to a reassessment of some classification criteria from the previous edition of the staging manual.

The revision of the breast cancer staging system officially began in January 1998, with the convocation of an AJCC consensus conference to review available data on serum markers or tumor markers as prognostic factors for breast cancer.¹⁵ Conference attendees concluded that there were insufficient data to support the incorporation of any of these markers into the TNM staging system for breast cancer. This conclusion was supported in consensus statements from the College of American Pathologists¹⁶ and the American Society of Clinical Oncology.¹⁷

A Breast Task Force composed of 19 internationally known experts in the field of breast cancer management was appointed by the AJCC to recommend changes in breast cancer staging that would reflect available clinical data and/or widespread clinical consensus about appropriate standards for the management of breast cancer. The newly revised TNM staging system for breast cancer, based on their recommendations, was first presented in print in

2002,^{11,18,19} and was officially adopted for use in tumor registries in January 2003.

General Principles of the TNM Staging System

The TNM staging system includes four classifications: clinical, pathologic, recurrence, and autopsy. Clinical classification (cTNM) is used to make local/regional treatment recommendations. It is based solely on evidence gathered before initial treatment of the primary tumor: physical examination, imaging studies (including mammography and ultrasound), and pathologic examination of the breast or other tissues obtained from biopsy as appropriate to establish the diagnosis of breast cancer. Pathologic classification (pTNM) is used to assess prognosis and to make recommendations for adjuvant treatment. It incorporates the results of clinical staging with evidence obtained from surgery and from detailed pathologic examination of the primary tumor, lymph nodes, and distant metastases (if present). Classification of a recurrent tumor (rTNM) is used when further treatment is needed for a tumor that has recurred after a disease-free interval and includes all information available at the time. Autopsy classification (aTNM) is used for cancers discovered after the death of a patient, when the cancer was not detected before death. Additional descriptors are used for identification

of special cases of cTNM or pTNM classifications, including the "m" prefix in cases with multiple tumors and the "y" prefix in cases where classification is performed during or following initial multimodality therapy (ie, neoadjuvant chemotherapy, radiation therapy, or both). Thus, ycTNM or ypTNM indicates the extent of tumor actually present at the time of that examination, rather than an estimate of tumor size before initiation of neoadjuvant therapy.

IMPLEMENTING THE REVISED STAGING SYSTEM FOR BREAST CANCER

Summary of Changes

The principal changes incorporated into the revised staging system for breast cancer (summarized in Table 1) are related to the size, number, location, and method of detection of regional metastases to the lymph nodes. These changes are of two types. Some reflect the growing use of new technology since the publication of the fifth edition, including SLNB, IHC staining, and molecular techniques such as reverse-transcriptase polymerase chain reaction (RT-PCR). Most changes proposed in this category define a nomenclature and coding system that will standardize the collection of important data that may affect treatment in the future. The most significant change in this category was the decision to distinguish between micrometastases and isolated tumor cells on the basis of size. Other changes are amendments of prior staging criteria, reflecting a recognition of the importance of absolute number of affected axillary nodes, and a reassessment of clinical outcomes associated with metastases to the infra- and supraclavicular nodes and internal mammary nodes. These amendments were made in cases where clinical evidence or widespread clinical consensus no longer supported a previous criterion.

TNM Classification of Breast Cancer

The TNM definitions for breast cancer from the sixth edition of the *AJCC Cancer Staging Manual* are shown in Table 2. In addition to the

detailed definitions given in Table 2, the additional guidelines outlined below should be noted.

For Assessment of Tumor Size (T)

- The clinical measurement used for classifying the primary tumor (T) is the one judged to be most accurate for that particular case (ie, physical examination or imaging such as mammography or ultrasound).
- The pathologic tumor size for classification is a measurement of only the invasive component.
- The size of the primary tumor is measured for T classification before any tissue is removed for special studies, such as for hormone receptors or HER2/neu status.
- In patients who have received multiple core biopsies, the original tumor size should be reconstructed based on a combination of imaging and all histologic findings.
- Carcinoma in situ with no evidence of an invasive component is classified as Tis, with a subclassification indicating type (ductal [DCIS] or lobular [LCIS]). Cases of ductal carcinoma in situ and cases with both ductal carcinoma in situ and lobular carcinoma in situ are classified Tis (DCIS).
- When there are multiple foci of microinvasion (extension of cancer cells beyond the basement membrane into the adjacent tissues with no focus greater than 1 mm in greatest dimension), the size of only the largest focus is used to classify the microinvasion. (Do not use the sum of all the individual foci.)
- In classifying multiple simultaneous ipsilateral primary carcinomas (infiltrating, macroscopically measurable), the largest primary carcinoma is used to designate T classification. Separate T classifications are *not* assigned to the smaller tumors, and the tumors are *not* added together to arrive at a T classification. Most conservatively, tumors are defined as arising independently only if they occur in different quadrants of the breast. The record should reflect that this is a case of multiple simultaneous ipsilateral primary

TABLE 1 Summary of Major Changes in the Sixth Edition of the AJCC Cancer Staging Manual for Breast Cancer

	Fifth Edition	Sixth Edition
Size of regional lymph-node metastases	Micrometastases were defined as tumor deposits not larger than 2.0 mm and classified as pN1a. No quantitative distinction was made between micrometastases and isolated tumor cells.	Micrometastases are distinguished from isolated tumor cells on the basis of size. Micrometastases are defined as tumor deposits larger than 0.2 mm but not larger than 2.0 mm and classified as pN1mi. Isolated tumor cells are defined as tumor deposits not larger than 0.2 mm identified by either standard histology or by immunohistochemical staining. They are classified as pN0(i+).
Number of regional lymph-node metastases	The number of affected axillary lymph nodes was considered only in subcategories of pN1.	Major classifications of lymph-node status are defined by the number of affected axillary lymph nodes.
Location of regional lymph-node metastases	Metastases in intracavicular lymph nodes (axillary level III) were considered equivalent to metastases in other axillary lymph nodes. Metastases to the internal mammary nodes were classified as N0/pN3.	Metastases in the intracavicular lymph nodes are classified as N3, because of their association with extremely poor prognosis. Metastases to the internal mammary nodes are classified as N1, N2, or N3, based on the size of the lesion and the presence or absence of concurrent axillary nodal involvement. Metastases to the supraclavicular lymph nodes are classified as N3.
The use of descriptors to indicate size and method of detection of nodal metastases	Metastases to the supraclavicular lymph nodes were classified as M1. No descriptors were used.	The descriptor (i+) is used to indicate the presence of isolated tumor cells no larger than 0.2 mm by either standard histology or by immunohistochemical staining. The descriptor (i-) means no detectable tumor cells by either histology or immunohistochemical staining. The descriptor (sn) is used to indicate that the staging classification was based solely on sentinel lymph node dissection. The descriptor (mol+) is used to designate cases that are negative by standard histologic staining for regional lymph node metastasis and in which reverse transcriptase-polymerase chain reaction was used to assess the node for tumor cells.

carcinomas. In the case of simultaneous bilateral breast carcinoma, each carcinoma is staged as a separate primary carcinoma.

- Dimpling of the skin, nipple retraction, or any other skin change except those described under T4b and T4 may occur in T1, T2, or T3 without changing the classification.

For Assessment of Regional Lymph Nodes (N)

- A case in which the classification is based only on SLNB is given the additional designation (sn) for "sentinel node," such as pN1 (sn). For a case in which an initial classification is based on SLNB but a standard axillary lymph node dissection is subsequently performed, the classification is

based on the total results of the axillary lymph node dissection (ie, including the sentinel node).

- Isolated tumor cells (ITCs) are distinguished from micrometastases primarily on the basis of size. They may be identified using standard hematoxylin and eosin (H&E) staining, IHC staining, or both.
- ITCs are defined as single cells or small clusters of cells not greater than 0.2 mm in largest dimension, usually with no histologic evidence of malignant activity (eg, proliferation or stromal reaction).
- Per a clarification of the AJCC staging system published in 2003,²⁰ the identifier (i) is used to indicate ITCs. All metastatic

TABLE 2 TNM Classification for Breast Cancer from the AJCC Cancer Staging Manual, 6th Edition

Classification	Definition
Primary tumor (T)	
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma in situ
Tis (DCIS)	Ductal carcinoma in situ
Tis (LCIS)	Lobular carcinoma in situ
Tis (Paget)	Paget disease of the nipple with no tumor (Paget disease associated with a tumor is classified according to the size of the tumor.)
T1	Tumor ≤ 2 cm in greatest dimension
T1mic	Microinvasion ≤ 0.1 cm in greatest dimension
T1a	Tumor > 0.1 cm but ≤ 0.5 cm in greatest dimension
T1b	Tumor > 0.5 cm but ≤ 1 cm in greatest dimension
T1c	Tumor > 1 cm but ≤ 2 cm in greatest dimension
T2	Tumor > 2 cm but ≤ 5 cm in greatest dimension
T3	Tumor > 5 cm in greatest dimension
T4	Tumor of any size with direct extension to chest wall or skin, only as described below
T4a	Extension to chest wall, not including pectoralis muscle
T4b	Edema (including peau d'orange) or ulceration of the skin of the breast, or satellite skin nodules confined to the same breast
T4c	Both T4a and T4b
T4d	Inflammatory carcinoma
Regional lymph nodes (N)	
NX	Regional lymph nodes cannot be assessed (eg, previously removed)
N0	No regional lymph node metastasis
N1	Metastasis in movable ipsilateral axillary lymph node(s)
N2	Metastases in ipsilateral axillary lymph nodes fixed or matted, or in clinically apparent* ipsilateral internal mammary nodes in the absence of clinically evident axillary lymph-node metastasis
N2a	Metastasis in ipsilateral axillary lymph nodes fixed to one another (matted) or to other structures
N2b	Metastasis only in clinically apparent* ipsilateral internal mammary nodes and in the absence of clinically evident axillary lymph-node metastasis
N3	Metastasis in ipsilateral infraclavicular lymph node(s), or in clinically apparent* ipsilateral internal mammary lymph node(s) and in the presence of clinically evident axillary lymph-node metastasis; or metastasis in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph-node involvement
N3a	Metastasis in ipsilateral infraclavicular lymph node(s) and axillary lymph node(s)
N3b	Metastasis in ipsilateral internal mammary lymph node(s) and axillary lymph node(s)
N3c	Metastasis in ipsilateral supraclavicular lymph node(s)
Regional lymph nodes (pN)	
pNX	Regional lymph nodes cannot be assessed (eg, previously removed or not removed for pathologic study)
pN0	No regional lymph node metastasis histologically, no additional examination for isolated tumor cells†
pN0(i-)	No regional lymph node metastasis histologically, negative immunohistochemical staining
pN0(i+)	Isolated tumor cells identified histologically or by positive immunohistochemical staining, no cluster > 0.2 mm‡
pN0(mol-)	No regional lymph-node metastasis histologically, negative molecular findings (RT-PCR)¶
pN0(mol+)	No regional lymph-node metastasis histologically, positive molecular findings (RT-PCR)¶
pN1	Metastasis in one to three axillary lymph nodes, and/or in internal mammary nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent*
pN1mi	Micrometastasis (> 0.2 mm, none > 2.0 mm)
pN1a	Metastasis in one to three axillary lymph nodes
pN1b	Metastasis in internal mammary nodes with microscopic disease detected by sentinel lymph-node dissection but not clinically apparent*
pN1c	Metastasis in one to three axillary lymph nodes** and in internal mammary lymph nodes with microscopic disease detected by sentinel lymph-node dissection but not clinically apparent*
pN2	Metastasis in four to nine axillary lymph nodes, or in clinically apparent* internal mammary lymph nodes in the absence of axillary lymph-node metastasis

Adapted from Greene, et al.,¹¹ with permission from Springer-Verlag.

(cont)

*Clinically apparent is defined as detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination.

†Classification is based on axillary lymph node dissection with or without sentinel lymph-node dissection. Classification based solely on sentinel lymph-node dissection without subsequent axillary lymph node dissection is designated (sn) for "sentinel node," such as pN0(i+)(sn).

‡Isolated tumor cells are defined as single tumor cells or small cell clusters ≤ 0.2 mm, usually detected only by immunohistochemical or molecular methods but which may be verified on hematoxylin and eosin stains. Isolated tumor cells do not usually show evidence of metastatic activity (eg, proliferation or stromal reaction).§Definition of (i+) was adapted in 2003 in order to be consistent with the updated International Union Against Cancer (UICC) classification.²⁰

¶RT-PCR: reverse transcriptase/polymerase chain reaction.

**If associated with more than three positive axillary lymph nodes, the internal mammary nodes are classified as pN3b to reflect increased tumor burden.

TABLE 2 TNM Classification for Breast Cancer from the AJCC Cancer Staging Manual, 6th Edition (cont)

Classification	Definition
pN2a	Metastasis in four to nine axillary lymph nodes (at least one tumor deposit ≥ 2.0 mm)
pN2b	Metastasis in clinically apparent internal mammary lymph nodes in the absence of axillary lymph-node metastasis
pN3	Metastasis in 10 or more axillary lymph nodes, or in intracavicular lymph nodes, or in clinically apparent ipsilateral internal mammary lymph nodes in the presence of one or more positive axillary lymph nodes; or in more than three axillary lymph nodes with clinically negative microscopic metastasis in internal mammary lymph nodes; or in ipsilateral supraclavicular lymph nodes
pN3a	Metastasis in 10 or more axillary lymph nodes (at least one tumor deposit ≥ 2.0 mm), or metastasis to the intracavicular lymph nodes
pN3b	Metastasis in clinically apparent ipsilateral internal mammary lymph nodes in the presence of one or more positive axillary lymph nodes; or in more than three axillary lymph nodes and in internal mammary lymph nodes with microscopic disease detected by sentinel lymph-node dissection but not clinically apparent
pN3c	Metastasis in ipsilateral supraclavicular lymph nodes
Distant metastasis (M)	
MX	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis

lesions not greater than 0.2 mm, whether detected by H&E staining or by IHC staining, are classified as pN0(i+). A classification of pN0(i-) is used to indicate no detectable tumor cells by either staining method. (Note: In the original sixth edition of the *AJCC Cancer Staging Manual*, the designation (i) was used to indicate whether IHC staining had been used. The amendment described above was made to ensure that the AJCC system was consistent with the current UICC system.)

- Micrometastases are defined as tumor deposits greater than 0.2 mm but not greater than 2.0 mm in largest dimension. Cases in which only micrometastases are detected (ie, none greater than 2 mm) are classified pN1mi.
- Metastatic lesions identified only through the use of RT-PCR are currently classified as pN0, because there are as yet insufficient data to determine whether such lesions are clinically significant.
- In cases where there are multiple metastatic lesions in a lymph node and deeper cuts of the node do not show a junction between two or more foci, classification is made according to the size of the largest lesion. If there is doubt, the lower category should be chosen.

For Assessment of Distant Metastasis (M)

- Cases where distant metastasis cannot be assessed are designated MX, cases in which

there is no distant metastasis are designated M0, and cases in which one or more distant metastases are identified are designated M1.

- A negative clinical history and examination are sufficient to designate a case as M0; extensive imaging or other testing is not required. Although some physicians are hesitant to assign a classification of M0, feeling that there is always a remote possibility that occult metastatic disease may exist, this is not appropriate under current staging guidelines.²¹ When the "X" classification is used, patients usually cannot have a stage assigned to their disease, making them ineligible for inclusion in cancer registries or as subjects for clinical trials.

CHALLENGES IN IMPLEMENTING THE SIXTH EDITION

The sixth edition of the *AJCC Cancer Staging Manual* contains some of the most extensive and significant revisions that have ever been made to the breast cancer staging system. Since the new guidelines were first published in September 2002, the AJCC has received many queries from clinicians about correct implementation of the revised system. We reviewed the submitted questions and identified some common themes, illustrated by the questions and answers below. (Note that some of these questions have to

do with topics that were left unchanged from the fifth edition.)

Identification and Measurement of ITCs and Micrometastases

Our pathologist does H&E staining on all his specimens and uses IHC staining only if nothing is found by H&E staining. Can IHC staining be used to identify micrometastases in lymph nodes?

The distinction between micrometastases and ITCs is now based on size alone. Metastatic cell deposits seen with IHC staining alone are considered to be equivalent to those seen on standard H&E staining.

In defining pN1 vs. pN0(i+), is it appropriate to measure size of the IHC micrometastasis to determine whether it exceeds 0.2 mm in any dimension? A case had negative H&E of a sentinel node and positive IHC with subsequent H&E verification. The maximum size was 0.19 mm on H&E and 0.71 mm on IHC.

This would be staged as pN1mi because we stage by greatest dimension regardless of the method of detection.

A sentinel node had a 1-mm metastatic lesion visible by H&E staining. IHC staining showed three additional small foci in the same lymph node, less than or just about equal to 1 mm. What is the pN designation?

If deeper cuts of the node do not show a contiguous process but confirm four separate foci, the classification would be pN1mi, reflecting the size of the largest lesion.

A sentinel node biopsy showed a single cluster of malignant cells with H&E staining measuring 0.18 mm. Results of IHC staining were unknown. Is this staged as pN1 because the malignant cells were detected by H&E?

The classification would be pN0(i+) because the cluster was less than 0.2 mm. It does not matter that the cells were detected by H&E staining.

If a breast carcinoma has one node with a micrometastasis and four nodes with ITCs, all found with IHC, is it staged pN1mi or do the other four ITC nodes upstage it?

ITCs defined as 0.2 mm or less would not upstage the patient.

Examination of the sentinel node in a patient with a primary tumor diagnosis of invasive lobular carcinoma revealed a large number of isolated tumor cells (<0.2 mm in diameter) dispersed throughout the nodal parenchyma in a diffuse pattern. How is this classified?

This is a common metastatic pattern for infiltrating lobular carcinoma. Although these are truly isolated tumor cells, most pathologists would classify this as pN1a based on the number of tumor cells.

Estimating the Size of the Primary Tumor

An invasive breast cancer was removed on stereotactic biopsy so no size was available clinically or pathologically. We classified this tumor as cTX/pTX. Is this correct?

Try to obtain a clinical size from the physician's notation of a palpable size and/or from mammographic or ultrasound imaging of the breast. In addition, because the small invasive tumor was removed entirely by stereotactic biopsy, it must have been less than 2 cm in size, so a classification of T1 would be appropriate.

If there was residual disease found in a re-lumpectomy or mastectomy specimen, does the patient need to be restaged to include the residual tumor?

If the relumpectomy or mastectomy was considered the definitive operation, then staging needs to be updated to include the findings of both the initial and the subsequent definitive breast cancer surgery.

When multiple tumors are present in the same breast, only the largest is measured to determine the T stage. How far apart do the tumors have to be to be considered separate?

Although various studies have suggested ways to make this determination quantitatively, it remains a judgment call. When the foci appear very close microscopically, a review of imaging studies may be useful in determining whether multiple lesions are present.

Classifying Tumors with Dermal Involvement

If there are tumor cells in the dermis without skin ulceration, peau d'orange, edema, or satellite nodules, what is the stage?

Direct skin invasion by AJCC criteria is defined as full-thickness involvement including the epidermis. If the epidermis is intact with only focal dermal involvement, this is not considered T4 but classified by the size of the primary tumor.

Pathology from a lumpectomy revealed a 2 × 1.5-cm mass extending into the skin up to the superficial dermis, without invasion of the epidermis. Is it a T1c or a T4?

This would be classified as T1c. As described above, if the epidermis is intact with only focal dermal involvement, classification is based on the size of the primary tumor.

A patient had breast cancer clinically described as a destructive lesion measuring 4 × 5 cm with obliteration of most of the nipple areolar complex. Biopsy revealed skin and subcutaneous (sc) tissue with infiltrating ductal carcinoma involving dermis and sc subareolar fibrous and muscular tissue. Would this be staged T4b?

Because pathology did not reveal epidermal involvement, this case would be classified as T2 because the greatest dimension of the primary tumor was not more than 5 cm. A tumor with clinically apparent involvement of the nipple areolar complex is classified as T4 if one or more of the following are present: full thickness direct invasive of the epidermis, satellite skin nodules in the same breast, and/or peau d'orange with invasion of the dermal lymphatics. Paget disease, which may involve obliteration of the nipple with no underlying invasive component, is classified as Tis (Paget).

Classification of Lymph Nodes in Unusual Locations

Is a positive intramammary node with negative axillary nodes classified as N1?

A positive intramammary node is considered as an axillary node in staging and thus would be N1 (provided that it is greater than 0.2 mm), even though the axillary nodes are negative.

If there is a nodule in the pectoral muscle not connected to a primary breast tumor, how is it coded?

If the nodule appears to represent involvement of the lymphatics associated with the pectoralis major muscle, it can be considered in the same

category as intramammary lymph node metastases or tumor deposits found in axillary fat without an associated lymph node, and classified as another positive axillary lymph node. However, if the nodule is within breast tissue and only adjacent to the fascia then it would be considered a satellite lesion and the T stage would be based on the index primary lesion.

Pathology reported one clearly identified lymph node negative for metastases, and 10 nodules of tumor ranging in size from 0.2 cm to 0.7 cm in the axillary fat. How is this coded?

Metastatic deposits within axillary fat are considered to be positive nodes. With 11 nodes examined and 10 positive, the classification would be pN3a (10 or more positive nodes).

THE FUTURE OF BREAST CANCER PROGNOSIS

The TNM system for cancer staging is not perfect, but it represents our current best effort to provide a method that is clinically useful and reflective of the available data. Refinements and amendments of the TNM system have been aimed at improving its ability to estimate prognosis. An important aspect of the new staging system is the definition of a nomenclature and coding system that will standardize the collection of important data that may affect treatment in the future. The most significant change in this category is the decision to distinguish between micrometastases and isolated tumor cells on the basis of size. Micrometastases, defined as lesions not greater than 2 mm in diameter, were recognized as clinically significant in the fifth edition of the *AJCC Cancer Staging Manual*,¹² but it seems likely that there is size limit below which this clinical significance would disappear. Lacking sufficient data to define this size limit, many clinicians are erring on the side of caution by aggressively treating all metastatic lesions, regardless of size. Since the publication of the sixth edition, a growing number of studies are using the AJCC criteria to evaluate outcome differences based on size in these minute lesions.

Although the sixth edition has given consideration to the relative importance of isolated tumor cells and micrometastases presenting as nodal

metastases, many researchers are now considering the possible prognostic significance of microscopic tumor-cell deposits that may appear in the bone marrow or peripheral blood. A recent pooled analysis by Braun, et al.²² (4,703 patients from nine studies) showed that bone marrow micrometastasis was a significant predictor of poor outcome in a multivariate analysis that included tumor size, lymph-node metastasis, tumor grade, and hormone-receptor expression as covariates. Although tumor-cell deposits in peripheral blood have recently been shown to be predictive of outcome in patients with metastatic breast cancer,²³ the small number of such cells in patients with early-stage breast cancer has hindered the accrual of similar data in these patients. New advances in identifying and collecting these cells should allow definitive studies to address this issue.

During the framing of the sixth edition of the *AJCC Cancer Staging Manual*, the Breast Task Force carefully considered whether the addition of histologic tumor grade or one of the molecular and biochemical markers associated with breast tumorigenesis could offer a significant improvement to the TNM system. It was enticing to think that the one or more of these markers could bring us closer to something that TNM currently does not provide—precise prognosis for the individual cancer patient. At that point in time, however, it was decided that the addition of any of these factors was not yet supported by sufficient data. The reasoning behind this decision has been extensively discussed elsewhere.^{11,19} For histologic grade, the data were sparse and too variable to allow a decision about how best to incorporate grade into the existing TNM system. Although some of the molecular and biochemical markers showed great promise for the future, lack of standardization in measurement techniques for many of them (for example, Ki-67, cathepsin D, HER2/*neu*, and p53) limit their current usefulness.

Although it is likely that tumor grade and selected other markers will again be seriously considered for incorporation into breast cancer staging for the seventh edition of the *AJCC Cancer Staging Manual*, more attention

is now turning to technological approaches that are able to chart the activity of hundreds or even thousands of genes simultaneously.

Over the last 35 years, research has convincingly demonstrated that literally hundreds of genetic and biochemical markers are associated with breast tumorigenesis. Researchers are now using molecular approaches to create a genetic fingerprint of the tumor based on the identification of genes that are actively expressed in tumor cells. For example, Van't Veer, et al. have used RNA-based microarrays to identify a 70-gene expression profile that was a more powerful predictor of 10-year survival rates for young patients with breast cancer than standard prognostic indicators based on clinical and histologic criteria.^{24,25} Soonmyung Paik from the National Surgical Adjuvant Breast and Bowel Project's pathology division recently presented a validation study for another system based on a panel of 16 cancer-related genes.²⁶ In this system, RNA is extracted from paraffin-embedded tumor sections and quantified using RT-PCR. He reported that this system is useful in determining prognosis in newly diagnosed breast cancer patients with Stage I/II, estrogen receptor-positive, node-negative disease who would normally receive tamoxifen as adjuvant therapy.

Such approaches to fingerprinting represent a powerful step forward in characterizing individual breast tumors, but they have yet to address the true complexity of the tumorigenic process. A microarray plate presents a static picture of gene activity associated with the malignant process, but this is somewhat misleading. It appears likely that hundreds of genes are turned on or off sequentially during a developmental process that is thought to involve a linear evolution from hyperplasia to carcinoma in situ to invasive carcinoma.²⁷ Another layer of complexity relates to the heterogeneity of malignant behavior among the cells of a breast tumor. Al-Hajj, et al.²⁸ suggest that most cells in a tumor permanently lack the capacity to proliferate to any significant degree; only a very small and phenotypically distinct subgroup of cells has this ability. They propose that this subpopulation of cells may derive from breast stem cells, retaining the ability for self-renewal and differentiation that is typical of normal

stem cells. If only a small population of phenotypically distinct cells is driving the tumorigenic process, then we may be forced to

rethink our strategies for fingerprinting tumor cells and for designing optimal treatment approaches.

REFERENCES

1. Halsted WS. The results of operation for the cure of cancer of the breast performed at the John Hopkins Hospital from June, 1889 to January, 1894. *Johns Hopkins Hosp Bull* 1894;1895; 4:297-321.
2. Haagensen CD. *Diseases of the Breast*. Philadelphia: WB Saunders; 1956.
3. Greenough RB. Varying degrees of malignancy in cancer of the breast. *J Cancer Res* 1925; 9:452-463.
4. UICC: Committee on Clinical Stage Classification and Applied Statistics. *Clinical Stage Classification and Presentation of Results, Malignant Tumors of the Breast and Larynx*. Paris: International Union Against Cancer; 1958.
5. Beales OH, Carr DT, Rubin P, eds. *Manual for Staging of Cancer*. Philadelphia: Lippincott; 1977.
6. Bland KI, Merck HR, Scott-Conner CE, et al. The National Cancer Data Base 10-year survey of breast carcinoma treatment at hospitals in the United States. *Cancer* 1998;83:1262-1273.
7. Anir H, Anzi MR, Makwaya CK, Jesani S. TNM classification and breast cancer in an African population: a descriptive study. *Cent Afr J Med* 1997;43:357-359.
8. Ben Ahmed S, Akoudou S, Bili M, et al. Breast cancer prognosis in Tunisian women: analysis of a hospital series of 729 patients. *Sante Publique* 2002;14:231-241.
9. Ikpat OF, Kuopio T, Ndumu-Egba R, Collins Y. Breast cancer in Nigeria and Finland: epidemiological, clinical and histological comparison. *Anticancer Res* 2002;22:3003-3012.
10. Vorobiof DA, Sita F, Vorobiof G. Breast cancer incidence in South Africa. *J Clin Oncol* 2001;19:1258-1275.
11. Greene FL, Page DL, Fleming ID, et al. *AJCC: Cancer Staging Manual*. 6th ed. New York: Springer; 2002.
12. Fleming ID, Cooper JS, Henson DE, et al, eds. *AJCC: Cancer Staging Manual*. 5th ed. Philadelphia: Lippincott-Raven; 1997.
13. Cady B, Scote MD, Schuler JG, et al. The new era in breast cancer: invasion, size, and nodal involvement dramatically decreasing as a result of mammographic screening. *Arch Surg* 1996;131: 301-308.
14. Haagensen C. *Diseases of the Breast*. Philadelphia: WB Saunders; 1986.
15. Yarbro JW, Page DL, Fielding JP, et al. American Joint Committee on Cancer Prognostic Factors Consensus Conference. *Cancer* 1999;86: 2436-2446.
16. Fitzgibbon PL, Page DL, Weaver D, et al. Prognostic factors in breast cancer: College of American Pathologists Consensus Statement 1999. *Arch Pathol Lab Med* 2000;124:966-978.
17. Buz RC Jr, Ravdin P, Hayes DF, et al. 2000 update of recommendations for the use of tumor markers in breast and colorectal cancer: clinical practice guidelines of the American Society of Clinical Oncology. *J Clin Oncol* 2001;19:1865-1878.
18. Sobin LH, Wittekind CH, eds. *TNM Classification of Malignant Tumors*. 6th edition. New York: Wiley-Liss; 2002.
19. Singletary SE, Allred C, Ashley P, et al. Revision of the American Joint Committee on Cancer Staging System for Breast Cancer. *J Clin Oncol* 2002;20:3628-3636.
20. Singletary SE, Greene FL, Sobin LH. Classification of isolated tumor cells: clarification of the 6th edition of the AJCC Cancer Staging Manual. *Cancer* 2003;98:2740-2741.
21. Greene FL, Brierly J, O'Sullivan B, et al. On the use and abuse of X in the TNM classification. *Cancer* 2005;103:647-649.
22. Braun S, Vogl FD, Naume B, et al. A pooled analysis of bone marrow micrometastasis in breast cancer. *N Engl J Med* 2005; 353:793-802.
23. Cristofarilli M, Hayes DF, Budd T, et al. Circulating tumor cells: a novel prognostic factor for newly diagnosed metastatic breast cancer. *J Clin Oncol* 2005;23:1420-1430.
24. Van't Veer LJ, Dai H, van de Vijver MJ, et al. Gene expression profiling predicts clinical outcome of breast cancer. *Nature* 2002;415:530-536.
25. Van de Vijver MJ, He UD, Van't Veer LJ, et al. A gene-expression signature as a predictor of survival in breast cancer. *N Engl J Med* 2002;347: 1999-2009.
26. Paik S, Shik S, Tang G, et al. A multigene assay to predict recurrence of tamoxifen-treated, node-negative breast cancer. *N Engl J Med* 2004; 351:2817-2826.
27. Singletary SE. A working model for the time sequence of genetic changes in breast tumorigenesis. *J Am Coll Surg* 2002;194:202-216.
28. Al-Hajj M, Wicha MS, Benito-Hernandez A, et al. Prospective identification of tumorigenic breast cancer cells. *PNAS* 2003; 100:3983-3988.

NBCCEDP BREAST CANCER EXPERT PANEL

WHITE PAPER ON TECHNOLOGIES FOR THE EARLY DETECTION OF BREAST CANCER

INTRODUCTION

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP), administered by the Centers for Disease Control and Prevention (CDC) helps low-income, uninsured, and underserved women gain access to lifesaving screening services for the early detection of breast and cervical cancers. The NBCCEDP is implemented in all 50 states, 4 U.S. territories, the District of Columbia, and 13 American Indian/Alaska Native organizations. Through these grantees, the program implements a wide range of activities, including a) public education to raise awareness of the benefits of screening and the availability of subsidized screening services; b) outreach to recruit high-risk women; c) provision of breast and cervical cancer screening exams and diagnostic testing; d) case management to facilitate access to care and assure completion of recommended follow-up testing; and e) professional education and quality assurance to ensure the highest standard of care for women in the program. Although the program has screened 1.9 million women and provided 4.6 million screening examinations since it was established in 1991, it reaches fewer than 20 percent of eligible women annually, primarily due to limited Congressional appropriations.

Fiscal management of the multifaceted NBCCEDP poses many challenges; one in particular is the determination of which screening tests should be paid by the program. Appropriate stewardship of federal funds requires that decisions be evidence-based, yet there are market factors that influence the daily realities of the program. Since the program's inception, research and scientific advances have resulted in both changing recommendations regarding the timing and subjects of screening, but also the introduction of new technologies. Determinations about whether the NBCCEDP should pay for newer screening tests and procedures are complicated. The program must balance a wide range of factors, including, for example, standards of care for women in the program, the public health mandate to serve as many women as possible, limited program funds, varying local health services infrastructures, and the impact of changes in program policies on program operating procedures and partners.

With regard to breast imaging, currently the NBCCEDP provides reimbursement for film mammography only. Digital mammography, magnetic resonance imaging (MRI), and ultrasound are not reimbursed as screening tests. Computer aided detection (CAD) of digital mammograms or of digitized films also is not reimbursed. These reimbursement policies are consistent with the U.S. Preventive Services Task Force (USPSTF) 2002 recommendations.¹ The USPSTF report reviewed studies of film mammography and clinical breast examination (CBE) screening, but did not explicitly address digital mammography, CAD, or ultrasound.

Recognizing the complexity of the task of reviewing NBCCEDP reimbursement policies and their considerable impact on individual BCCEDP programs, CDC initially sought to gather information about programs' experiences with current reimbursement policies. Key informant

interviews with NBCCEDP Program Directors representing eight state programs and two CDC program staff were conducted to identify the range of issues that should be considered in CDC's reconsideration of reimbursement policies. The report of these interview findings is presented in Appendix A. Additionally, CDC identified key scientific references to provide general background about current and newer technologies. Evidence overviews and discussions with experts revealed a lack of scientific evidence in many relevant areas, particularly direct comparisons of test performance characteristics, such as sensitivity and specificity, and in utilization patterns among the technologies. Also evident from these sources was the lack of a clear and consistent definition of 'high risk' for breast cancer. One reason for this inconsistency is that definitions of risk used in studies and public health shift as new scientific evidence emerges. Most studies assessing new screening technologies for use among women at high risk define high risk as either those with BRCA 1/2 or a family history of breast cancer. In the context of this paper, discussions of the use of new technologies directed to women at high risk relies on the various definitions used in current studies. The panel does recommend further work, however, to more clearly define concepts of risk within the NBCCEDP.

Because of the complexity of program issues and the paucity of directly relevant scientific evidence, the CDC sought to implement a review process relying primarily on expert opinion to guide its decision-making. An expert panel was established including researchers, clinicians, public health practitioners and NBCCEDP Program Directors. A list of expert panel members is included in Appendix B. This expert panel was charged with a) identifying minimum criteria for establishing new reimbursement policies, b) identifying a framework of issues to be considered in policy review, c) providing specific recommendations for reimbursement policies, and d) providing guidance concerning procedures for future reviews of reimbursement policies.

Members of the expert panel on breast cancer reimbursement policies conferred in subgroups and as a full committee through a series of conference calls and a face-to-face meeting held in Atlanta on March 29 and 30, 2005. This report provides the background for and final recommendations of this expert panel. The first two sections of this paper provide general information about the epidemiology of breast cancer and the women served by the NBCCEDP. The next two sections provide context for assessing individual technologies by defining the minimum criteria that must be met in order to recommend reimbursement and the specific test characteristics and public health factors that must be assessed in making reimbursement policy decisions. The final two sections specifically review the test characteristics and public health factors for each technology under consideration and present the expert panel's recommendations for reimbursement policies as well as recommendations for additional research and surveillance to provide a firmer foundation for future assessments of program policies.

BREAST CANCER

Breast cancer is the most frequently diagnosed cancer among women in the United States and the second leading cause of cancer death. An estimated 211,240 women will learn they have breast cancer and an additional 40,410 will die from breast cancer in the United States in 2005. A woman's chances of being diagnosed with breast cancer sometime during her life are about 1 in 7 and her chances of dying from breast cancer are about 1 in 33. Currently, just over 2 million

women in the United States have been diagnosed with and treated for breast cancer. Although the disease is most prevalent among women, 1,690 men also will be diagnosed with breast cancer and 460 men will die from the disease in 2005.

In addition to the new cases of invasive breast cancer that will be identified in 2005, 58,490 new cases of in situ breast cancer will be identified as well. Almost 85 percent of these will be ductal carcinoma in situ (DCIS).² In situ cancers are an early stage of cancer, when the disease is still confined to its site of origin. Increases in the detection of these early stage cancers are a direct result of screening with mammography. DCIS is estimated to account for as much as 20 percent of all cancers diagnosed by mammography, about 1 in every 1,300 mammograms. Mammography has been shown to be better at detecting DCIS than invasive cancers, in one study finding 86 percent of DCIS cases and 75 percent of invasive breast cancers.³

While the use of mammography to find early stage breast cancers before physical signs of disease are evident is attributed with overall reductions in breast cancer mortality over the past decade, mammography does have limitations.² Mammography is estimated to miss as many as 25 percent of cancers and about 10 percent of findings require additional testing in women who later are found not to have breast cancer.^{4,5} However, routine mammography screening among asymptomatic, age-appropriate women to detect early stage breast cancers remains the best public health defense against breast cancer. Despite the identification of several risk factors for breast cancer, such as increasing age, family history of breast cancer, high breast tissue density, and inherited genetic mutations, more than 50 percent of breast cancers occur in women with no known risk factors.²

SCREENING FOR BREAST CANCER IN THE NBCCEDP

The NBCCEDP serves low-income, uninsured women. When the NBCCEDP began in 1991, CDC followed recommendations for breast cancer screening that emphasized the value of screening mammography both for women 40–49 years of age and for women 50 years of age and older. CDC funded programs were permitted to establish their own age guidelines within these parameters. In 1994, however, the NBCCEDP established a more stringent policy for funding breast cancer screening that was consistent with the best use of very limited resources. The new NBCCEDP policy required that at least 75 percent of mammograms paid with NBCCEDP funds be provided to women 50 years of age or older. In addition, in 1998, when Medicare began to pay for screening mammography, NBCCEDP policy changed to exclude women 65 years of age with Medicare Part B coverage. Over time, these changes have produced an age shift in women screened in the program. Although about 48 percent of mammograms were provided to women ages 50–64 in the first 5 years of NBCCEDP screening, this proportion has increased to 72 percent in the most recent 5 years (2000–2004).

Looking at aggregate data from 1991–2002, approximately 50 percent of the women screened in the program are white. Increasing focus on recruiting foreign-born women and those least likely to be previously screened, however, lowered this proportion to 43 percent from 2001–02, with corresponding increases among minority women, particularly Hispanic women and Asian/Native Hawaiian, and Pacific Islanders.⁶

A study of re-screening in four NBCCEDP programs found that 72 percent of women in these programs were re-screened within 18 months and 82 percent within 30 months, which is similar to the proportion of women in the general population that have been re-screened. Hispanics, women with a history of breast cancer before their initial program mammogram, and women who had used hormone replacement therapy before their initial program mammogram, were more likely to have been re-screened at 30 months.⁷

Approximately 11 percent of first round screening mammograms performed by the program between 1991 and 2002 were abnormal. This proportion decreased to about 7 percent for second round mammograms. The percentage of women reporting symptoms also was greater in the first screening round than in subsequent rounds (11 vs. 7 percent, respectively). The proportion of abnormal screening mammograms decreased with increasing age during this same time period (12 percent in women 40 to 49 years of age vs. 7 percent in women 65 years of age and older).⁶

Between 1991 and 2002, 9,956 women were diagnosed with invasive breast cancer through the NBCCEDP. Seventy four percent of these cancers were identified at an early stage (stage I or II). Overall and adjusted for age, about 9.4 cases of in situ or invasive breast cancer are diagnosed per 1,000 mammograms in the NBCCEDP. This rate is higher in white women, but lower in all other racial and ethnic groups. Regardless of age, race, or ethnicity, the detection rates for carcinoma in situ and invasive cancer were substantially lower in subsequent screening rounds compared to the initial program screening.⁶

REIMBURSEMENT DECISION CRITERIA

Review of NBCCEDP reimbursement for new screening technologies must consider the overall advantages and disadvantages of the new technology relative to the mission of the NBCCEDP and current screening approaches. Because screening is performed on healthy, asymptomatic women, each new technology must clearly demonstrate its ability to perform equally to or better than current technologies. Overall the technology must meet certain minimum criteria. These include:

- Reduce Breast Cancer Morbidity and Mortality – The technology must contribute to reductions in morbidity and mortality across the population of program eligible women. For breast cancer screening, reductions in morbidity and mortality come from identifying and treating early stage cancers including in situ carcinomas.
- Sustain or Enhance Overall Public Health Benefit – Use of the technology should sustain or enhance the number of program eligible women served by the NBCCEDP, for example by maintaining or increasing access to services or maintaining or increasing dollars available to pay for services.
- Sustain or Enhance Overall Quality of Care – Use of the technology should sustain or enhance the quality of services provided by the NBCCEDP, for example by maintaining or enhancing effectiveness, reducing false positive findings, or improving test acceptability and patient adherence.
- Sustain or Enhance Overall Program Operations – Use of the technology should sustain or enhance program operations across NBCCEDP sites, for example by

- streamlining administrative procedures, maintaining or increasing provider enrollment, or enhancing clinical efficiency.
- Reduce Overall Health Disparities – Use of the technology should further NBCCEDP goals to reduce disparities in the delivery of services to and health outcomes of low-income, uninsured, and underserved women.

Beyond these minimum criteria for establishing reimbursement policies, consideration must be given to two additional factors. First, policies must accommodate differences across programs. NBCCEDP programs differ considerably in public health infrastructures as well as local health care capacities and systems. Reimbursement policies must be consistent across programs while still affording flexibility in how NBCCEDP programs implement these policies across local communities.

Second, as a federal government agency, the CDC must consider related policies established by other federal agencies, in particular the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS). Each federal agency establishes policies consistent with its unique mission. Unlike the CDC, FDA and CMS are regulatory agencies. The FDA provides market approval for new drugs and devices and CMS provides payment approval and establishes reimbursement rates for the delivery of medical services under mandated federal entitlement programs. The NBCCEDP relies on the rate structure established by CMS for reimbursement of early detection and diagnostic services in Medicare and it is statutorily mandated that NBCCEDP reimbursement not exceed these Medicare rates.

Reflective of the different missions of these agencies, the procedures each uses to establish policies differ. FDA seeks to establish whether a medical drug or device is safe and as effective as existing drugs or devices. FDA relies in part on input from industry and industry-sponsored studies in making this determination.⁸ CMS seeks to identify medical procedures for reimbursement under Medicare and Medicaid. Its determinations are based on whether a procedure, device, or technology is “reasonable and necessary” for the diagnosis and treatment of a medical condition.⁹ Like the FDA, CMS also invites industry collaboration and comment during their approval process. Importantly, however, neither CMS nor FDA approval of a new procedure, drug, device, or technology indicates that it is *more* effective than existing procedures, drugs, devices or technologies.

Some components of these approval procedures overlap across federal agencies. For example, CMS requires that drugs or devices be approved as safe and effective by the FDA before it will provide approval for reimbursement under Medicare or Medicaid. But it is also true that some components remain independent. For example, CMS provides approval for some procedures, such as counseling about preventive service, that do not fall within the authority of FDA’s mandate to establish safety and efficacy because it is not a drug or device.

Establishment of reimbursement policies under CDC’s NBCCEDP must first reflect the unique mission of the program, maximizing reductions in breast cancer morbidity and mortality in the eligible population of low-income, uninsured women. Procedures for establishing these policies rely primarily on scientific evidence, expert opinion, and program considerations. In this context it is not surprising that CDC policies in some cases will overlap with those of the FDA and CMS,

while in others they may not. For example, while CDC might require that all reimbursed technologies be approved by FDA as safe and effective for the same use, there may be program services for which FDA has no authority (e.g., preventive services counseling). Similarly, there may be circumstances where CMS has approved a technology or procedure and established associated reimbursement rates, but the benefits of the technology for the NBCCEDP are outweighed by disadvantages such as high costs, lack of clinical availability, or program inefficiencies.

For these reasons, absolute requirements for FDA and/or CMS approval for all NBCCEDP reimbursed technologies were considered overly restrictive. Further, any requirement that the NBCCEDP reimburse for all FDA and/or CMS approved technologies was considered inappropriate as this might result in limiting the program's ability to achieve its mission to extend services to as many eligible women as possible in order to maximize reductions in breast cancer morbidity and mortality. Thus, it is recommended that:

- for all technologies and procedures within FDA authority, the technology should be approved by the FDA for the use under consideration, and
- for all technologies and procedures within CMS authority, the technology should be approved by CMS and have established Medicare rates, but not all CMS approved technologies need to be reimbursed by the NBCCEDP.

BASIS FOR TECHNOLOGIES ASSESSMENT

The basis for decisions about whether the NBCCEDP should provide reimbursement for any new technology combines the full range of test characteristics as well as program factors. This section presents an overview of the components of this assessment. These issues combine uniquely for each technology. For example, some new technologies bring more favorable test characteristics, but at a test or program cost that on balance does not support the overall public health goals of the NBCCEDP. Other new technologies might bring only comparable test performance characteristics, but add program efficiencies or reduce test costs that potentially allow more women to be screened by the program.

Test Characteristics

Test characteristics include a combination of five performance and cost characteristics that will be unique for each technology. Comparison of technologies across these characteristics provides the basis for assessing test-specific advantages and disadvantages. These characteristics include:

Accuracy – test accuracy in identifying early stage breast cancers is reflected in several measures, including sensitivity, specificity, positive predictive value, negative predictive value and level of test uncertainty. Sensitivity and specificity are related measures. Sensitivity refers to the proportion of all true cancers detected by a test within a specified timeframe, usually one year. Specificity refers to the proportion of true negative results (e.g., no cancer present) for which a negative test result is obtained within a specified timeframe, usually one year. High sensitivity increases the probability that cancers will not be missed while high specificity reduces the probability that women will undergo unnecessary follow-up procedures, such as repeat mammograms, adjunctive imaging (ultrasound or MRI), fine needle aspiration, and biopsies.

While the negative consequences of missing cancers are high, the adverse physical and emotional consequences of unnecessary medical procedures also are high. For any single test, specificity generally decreases as sensitivity increases.

From a public health perspective, the trade-offs between different levels of test sensitivity and specificity is substantial. For example, in a population of 100,000 women for which a true prevalence of cancer is 5 percent, 95,000 women would be normal (95 percent) and 5,000 would have cancer. A test having a sensitivity of 80 percent would find 4,000 cancers, but would miss 1,000 cancers. An increase in test sensitivity of 10 percent, to a sensitivity of 90 percent, would result in half as many missed cancers, or 500 fewer missed cancers. More dramatically, however, if test specificity is 90 percent, 10 percent of the 95,000 women without cancer would receive a false-positive result. In this scenario, 9,500 women would incorrectly receive a positive test result. A 5 percent absolute decrease in specificity to 85 percent translates into an additional 4,750 women receiving a false-positive test result. Decreases in test specificity which often accompany improvements in sensitivity can yield substantial increases in follow-up tests such as image guided needle biopsies that do not result in a diagnosis of malignancy and the costs associated with unnecessary follow-up tests. In the example given, an additional detection of 100 cancers came at a cost of additional work up of 4,950 normal women. The critical issue for any test is the extent to which both sensitivity and specificity can be balanced to yield an optimal public health outcome.

Two additional related measures, positive and negative predictive value, also provide valuable information about test performance. These measures assess the diagnostic value of a test. Positive predictive value reflects the proportion of times a positive test finding leads to diagnosis of disease, while negative predictive value reflects the proportion of times a negative test finding is obtained among women who do not have cancer. Similar to the scenarios described above for test sensitivity and specificity, the consequences of low positive predictive value (PPV) are realized in missed cancers and the consequences of low negative predictive value (NPV) are realized in unnecessary follow-up tests and patient anxiety.

One final indicator of test accuracy is the level of uncertainty about test results. Uncertainty can result for example, from ambiguity in a test image or lack of clarity about interpretation of specific image characteristics.

Reproducibility - Test reproducibility refers to the consistency of the image or sample produced by the test as well as the consistency of interpretation of the image or sample. Reproducibility is particularly relevant for an examination in which subsequent images are compared to a baseline image, such as with mammography. Poor reproducibility can result in repeat screening examinations to enhance overall test precision.

Population Characteristics – Some tests perform better among women with certain characteristics, particularly for imaging technologies. For example, image capture or display characteristics might accentuate identification of abnormalities in dense breasts or testing procedures might reduce patient discomfort and potentially increase compliance. Test characteristics that maximized test performance among subpopulations may introduce important

new benefits, but also can introduce challenges and potentially additional costs associated with outreach, communications and monitoring in NBCCEDP programs.

Interval – Screening interval refers to the recommended time to repeat routine screening following a normal test. Frequent screening can lead to increased costs because more tests are performed. But particularly long screening intervals reduce the lead time gained from more frequent screening and can introduce compliance problems, particularly if the interval differs from normal health routines.

Test Cost – All procedures reimbursed by the NBCCEDP are reimbursed at current Medicare rates. As reflected in Table 1 for the technologies being reviewed in this white paper, these rates vary across regions and technologies. These Medicare test reimbursement rates reflect lab and test costs and do not include the professional component. Generally, new technologies cost more initially on a per-test basis than existing technologies, although costs of new technologies tend to fall as adoption rises. The primary issue when comparing costs across technologies is the incremental cost difference between the new compared with the older technology.

Table 1: 2005 Medicare Reimbursement Rates¹⁰					
CPT Code	Procedure	Low	High	Average	Median
76092	Screening Mammogram, Conventional, Bilateral	\$66.53	\$143.03	\$86.82	\$84.58
76090	Diagnostic Mammogram, Conventional, Unilateral	\$61.62	\$131.01	\$79.53	\$77.51
76091	Diagnostic Mammogram, Conventional, Bilateral	\$76.54	\$162.65	\$98.75	\$96.24
76082	CAD, w/ 76090, 76091, G0206, or G0204	\$14.23	\$32.91	\$19.97	\$19.23
76083	CAD, w/ 76092 or G0202	\$14.23	\$32.91	\$19.97	\$19.23
G0202	Screening Mammogram, Digital, Bilateral	\$101.53	\$225.94	\$137.24	\$132.14
G0204	Diagnostic Mammogram, Digital, Bilateral	\$108.33	\$237.97	\$144.55	\$139.37
G0206	Diagnostic Mammogram, Digital, Unilateral	\$87.53	\$192.40	\$116.87	\$112.68
76093	MRI, Breast, Unilateral	\$556.49	\$1,314.51	\$797.14	\$769.31
76094	MRI, Breast, Bilateral	\$727.71	\$1,732.85	\$1,050.75	\$1,013.17
76645	Breast Ultrasound, Unilateral/Bilateral (single rate)	\$54.12	\$117.08	\$71.07	\$69.16

Public Health Factors

Public health factors include a combination of clinical, patient, and program factors. Similar to test characteristics, each of these factors can have a large influence on the ability of the NBCCEDP programs to realize reductions in breast cancer morbidity and mortality. Unlike test characteristics, however, public health factors vary considerably across NBCCEDP programs. This variability is not systematically monitored and can be difficult to assess. Key informant interviews were conducted with select NBCCEDP sites to expand available information about the range of issues encountered by programs. But information about the prevalence of these issues across programs is not generally available. For this reason, recommendations are also

presented in this white paper for research and surveillance initiatives that might enhance public health information for future policy reviews.

Clinical Factors – Three types of clinical factors are considered in assessing test reimbursement, including practice patterns, clinical efficiency, and patient education requirements. Practice patterns refer to differences in adoption of new technologies across program localities. In localities where providers primarily utilize a technology that is not approved for reimbursement, the program provides reimbursement at the rate of the approved technology. But newer technologies often are more expensive, and the added cost difference must either be absorbed by providers or reimbursed through alternative funds, placing added strain on providers as well as on alternate funding sources. Further, as providers transition to newer technologies they perform older tests at lower frequencies, potentially reducing their proficiency. These situations also can reduce the efficiency of clinical practice. Finally, many new technologies require additional patient education. The clinical time associated with educating patients about the appropriate use of new technologies and interpretation of findings is an additional factor for consideration. The media, industry, and providers can add to this pressure by marketing new technologies directly to women, creating demand for services that are not reimbursable under the program.

Patient Factors – Patient factors relevant to the overall benefit of providing a particular technology through the NBCCEDP include the acceptability of the technology, compliance, the burden of disease and screening history among those appropriately screened by the technology, as well as quality of life impact. Acceptability by patients is influenced by a variety of factors, including the level of discomfort associated with the test as well as perceived disease risk and test benefits. Women's perceptions of their personal risk of getting breast cancer are considerably higher than their actual risk and they overestimate the benefits of breast cancer screening.¹¹ Thus women generally accept some test discomfort to ensure that a diagnosis of cancer is not missed. However, it is also true that poor test acceptability can cause delays in initial or routine screening. Further, controversial tests receiving media attention can stimulate confusion that dissuades women from receiving any test at all.¹¹

Patient characteristics, such as age, risk, and prior screening history, significantly influence the likelihood of finding breast cancer, and as a result change the cost/benefit estimate of screening. These are important considerations when assessing program benefits of reimbursement for technologies whose test performance varies across these patient characteristics. Finally, patient quality of life related to test characteristics is an important consideration. Despite women's willingness to accept additional procedures or discomfort to reduce their personal risk of dying from breast cancer, the consequences of these procedures and associated non-medical patient costs, such as time lost from work or child care expenses, are not trivial.¹²

Program Factors – Program factors play an important role in assessing the overall advantages and disadvantages of providing reimbursement for new technologies. Introduction of new technologies can influence program efficiency, provider enrollment, and women's access to program services. Program efficiencies can be either enhanced or reduced by changes in requirements for provider communication, patient outreach and education, and administrative procedures. When new technologies are accepted for reimbursement by the program, considerable program staff time is required to educate providers about new policies and

procedures, make modifications to reimbursement systems, modify data and reporting systems, and amend contracts with clinical providers. Providers similarly need time to implement new office procedures. But the converse is also true when providers are using technologies that are not reimbursed by the program. Providers need to find alternate funding to cover cost differentials. This takes time and resources, not only to find separate sources of funds, but also to establish systems that account for these separate funding sources.

Providers are essential to the NBCCEDP. Reimbursement policies can, in some rare circumstances, cause providers to drop out of the program altogether. This reduces the number of providers delivering services for the program and thereby reduces program access for women. Reduced provider capacity can both limit the programs' ability to meet demand for early detection services and cause delays in providing needed services. Callbacks introduce another barrier to program access when women must travel back to a facility to be retested.

Key informant interviews also revealed the potential for some reimbursement policies to adversely affect program credibility. Failure to reimburse technologies that have become common can convey an image of the program as 'out of step' with current practices or leave an impression that women in the program receive 'less than optimal' care. Educating patients and providers about the basis for reimbursement policies and the advantages and disadvantages of new technologies is an important program activity, which in these cases may require additional staff time and skill.

TECHNOLOGIES OVERVIEW

This section provides an overview of the relevant test characteristics and public health factors for breast cancer screening technologies currently reimbursed by the NBCCEDP and those being considered for reimbursement as screening tests. These tests include film mammography, digital mammography, computer assisted detection (CAD), magnetic resonance imaging (MRI), and ultrasound. Mammography and CAD are currently approved by the FDA and CMS for breast cancer screening, while MRI and ultrasound are approved only as diagnostic tests.

Film Mammography

Test Characteristics – The overall accuracy of film mammography is high. Film mammography yields significant reductions in breast cancer mortality, ranging from 21-30 percent^{13,14,15,16} and has resulted in an overall shift toward detection of small, low-grade tumors that have a better, long-term prognoses.^{17, 18} Film mammography sensitivity varies as a function of breast density, achieving levels as high as 98 percent in fatty breasts and 84 percent in dense breasts.^{16, 19} One recent study found sensitivities ranging from 63 percent in dense breasts to 87 percent in fatty breasts.⁴

The reproducibility of film mammography images and interpretation also are generally high. The technology has been used in clinical practice for more than 30 years and reporting and quality assurance systems are well established. The BI-RADS[®] system for film interpretation has undergone four revisions since its inception in 1992.

All major U.S. medical organizations recommend screening film mammography, with or without CBE, for women 40 years of age and older.^{1,2,12,20} The NBCCEDP emphasizes use of screening mammography in women 50 years of age and older by requiring that 75 percent of program mammograms be provided to this group. As reflected in Table 1, film mammography is one of the least expensive breast cancer screening tests currently available.

Public Health Factors – Film mammography is widely available²¹ and systems for quality assurance and uniform reporting are well established. Film mammography is a completely portable system, offering women the ability to take films from one center to another as needed. However, different procedures for reading film images, such as batch interpretation, can influence repeat testing not associated with an abnormal finding. Facilities that rely on batch interpretation without immediate review require that a woman return for a diagnostic mammogram for problems identified on the screening exam. Facilities that use batch interpretation, however, tend to have lower recall rates than facilities that perform online interpretation of mammograms.

Screening with film mammography has considerable market penetration. A recent study found that 60 percent of women had had their first mammogram by the end of their 40th year and almost 90 percent had begun screening by 50 years of age.²² Even among subpopulations having large barriers to routine medical care, high rates of mammography screening are evident. Women without private health insurance began screening at a median age of 46.6 years.²² Women who did not speak English began screening at a median age of 49.3 years.²² And even among women with no private health insurance and who don't speak English mammography screening was initiated at a median age of 55.3 years.²² While these rates of initial screening are encouraging, rates of routine screening are lower and vary considerably by region. Among women 50 years of age and older in the United States, 20 percent reported not having received a mammogram within the past 2 years. This rate varied from 12 to 31 percent across states.²³

Digital Mammography

Test Characteristics – The accuracy of digital mammography appears to be comparable to that of film mammography.²⁰ Three prospective screening trials, two with the women acting as their own control and one randomized trial comparing film mammography to digital mammography, demonstrated no statistically significant difference in sensitivity.²⁴⁻²⁷ One trial demonstrated that digital mammography had a statistically significant lower recall rate than film mammography,^{24, 25} while one showed no difference,²⁶ and the other showed a statistically significant higher recall rate.²⁷ Most differences between screen and digital mammography are thought to be due to technique rather than modality.^{24, 25} Additional data about the relative diagnostic accuracy and cost-effectiveness of digital compared to film mammography are expected within the next year from the Digital Mammographic Imaging Screening Trial (DMIST), a multi-center trial sponsored by the National Cancer Institute and coordinated by the American College of Radiology Imaging Network.

As a newer technology, systems for quality assurance and standardization of digital mammography are less well established than those for film mammography. Unlike film

mammography, the image capture and display components of digital mammography are separated and there is considerable variability for each of these elements across different digital systems. Programming differences in image capture not only affect the characteristics of the image and thus reproducibility across systems, but also the ability to transfer images to other systems as a woman moves through the health care system. Differences in display characteristics, such as pixel size and contrast, also affect the reproducibility of image interpretation.

Recommended screening intervals using digital mammography are the same as those for film mammography. As reflected in Table 1, however, digital mammography costs much more than film mammography, approximately \$55 more per screening examination. These increased costs and the costs associated with potentially higher recall rates could substantially reduce the overall number of screening examinations that could be provided through the NBCCEDP within existing appropriation levels.

Public Health Factors – As of 2003, only 413 full field digital mammography units were accredited under the Mammography Quality Standards Act (MQSA) in the United States.²⁸ It is estimated that 6.8 percent of all mammography facilities use digital mammography, although these are generally high-volume facilities (Personal Communications, Pamela A. Wilcox). While market penetration of digital mammography is generally low at this time, it is anticipated that this may change due to direct marketing of the technology. Digital manufacturers have launched extensive market campaigns to both medical centers and the public. Facilities, having made substantial investments in the technology, also have marketed digital mammography to the public extensively as they seek to recover their capital expenditures. These factors have inflated the perceived value of the technology, at least based on current evidence, and have stimulated public demand. Further increases in the adoption of digital mammography may depend greatly on the results of the DMIST trial.

Because few facilities use digital mammography, few NBCCEDP programs have noted problems with provider enrollment or program access due to the lack of reimbursement for this technology. However, because high volume facilities appear more likely to be using digital mammography, the lack of reimbursement for digital mammography may have a disproportionate impact of failure to reimburse for digital mammography in some areas.

From the perspective of the patient, the acceptability of film and digital mammography are comparable. The tests are virtually indistinguishable at the point of image capture. As a result of this and equivalent screening intervals, compliance appears equal across film and digital mammography.

CAD

Test Characteristics – CAD is not a screening technology but a detection aid and it is unclear whether CAD improves the accuracy of screening mammography. Evidence suggests that cancer detection rates may be slightly enhanced by using CAD,^{25, 29} particularly among less experienced radiologists.³⁰ One large prospective community-based study comparing breast cancer detection with and without CAD demonstrated a cancer detection rate of 3.2 cancers/1000

women screened without CAD and 3.8 cancers/1000 women screened with CAD, a 19.5 percent increase. However, these higher detection rates appear to come at the expense of increased recall rates. Recall rates in this same study increased from 6.5 to 7.7 percent.^{25, 29} Using a non-commercial CAD system in a screening situation, Helvie et al.³¹ detected 10/11 malignancies for a 91 percent sensitivity, which was identical to the radiologists' sensitivity. The missed cancer was different for each modality. Due to CAD results, recall increased 9.7 percent, from 14.4 to 15.8 percent. Interestingly, in a 1-year follow-up, five patients developed cancer, two of whom were marked by CAD the preceding year. In a recent article by Gur, et al.,³⁰ the recall rate for 24 radiologists interpreting 115,751 screening mammograms (59,139 with CAD and 56,432 without CAD), demonstrated a similar recall rate with and without CAD (11.39 versus 11.4 percent, respectively) and similar breast cancer detection rates with and without CAD (3.49 versus 3.55/1000, respectively). These data, however, were not adjusted for possible differences in the characteristics of the women screened and whether the examination was the woman's first or subsequent exam.

Different algorithms are used in different CAD systems and no evidence is available about differences across these systems or the reproducibility of interpretation results. Algorithms have been refined over time and these refinements have proceeded even for systems within clinical trials. Further, procedures for how CAD is used to complement radiologists' review of digital images are not uniform. CAD adds approximately \$20 to the cost of a screening mammogram, and CAD has been shown to substantially increase the amount of time needed to interpret each mammogram.

Public Health Factors – CAD is widely available and is rapidly achieving substantial market penetration. CAD introduces an additional step in the interpretation process. Following initial review and interpretation of mammography images, CAD results are reviewed and the mammography images may then be re-reviewed to assess specific CAD findings. Thus, use of CAD would not be expected to increase clinical efficiency. Among potential concerns are that CAD may be reviewed before initial interpretation and that CAD may alter radiologists' normal search and decision-making process. Over reliance on CAD prompts could limit search in some areas of the digital image.^{32, 33} And while CAD may provide an objective source of information in litigation, there also is evidence of misuse of the technology by litigators to generate independent interpretations of digital images without radiologists' involvement.

While CAD is intended to be used after the initial interpretation of the mammogram to assure that results do not bias the radiologists' interpretation, there are numerous anecdotal reports that CAD results are reviewed while mammograms are being interpreted. The studies that have assessed CAD have carefully limited its use as an adjunct after the initial interpretation of a mammogram. It is possible that the results of these CAD studies are not generalizable to community practice. As a result, community recall rates from CAD may be even higher than those found in studies.

MRI

Test Characteristics – MRI is not a primary screening test for women at average risk for breast cancer. MRI has been used to detect malignancies in women who have problematic diagnostic

mammograms or unknown primary malignancies, to detect recurrences in women who have been treated conservatively for breast cancer, and/or to search for additional occult foci in women with a known malignancy. Studies of MRI have primarily assessed MRI as a screening test for breast cancer in women high-risk for the disease (e.g., BRCA1/2 carriers).

Studies of MRI among women at high risk for breast cancer demonstrate substantially higher sensitivity than mammography in detecting cancer. Warner, et al.,³⁴ reported sensitivities among women at high risk for breast cancer of approximately 36 percent for mammography compared to 77 percent for MRI, using BI-RADS® 1 to 3B as negative findings. Using similar criteria, Kriege et al.³⁵ reported sensitivities of 24 percent and 47 percent for mammography and MRI, respectively. When Kriege et al.³⁵ included BI-RADS® 3 as abnormal, sensitivities for mammography and MRI were 40 percent and 71 percent, respectively. However, these higher sensitivities also come with lower specificity.²⁰ Approximately 10 to 25 percent of high risk women screened with MRI received a false-positive result.^{34, 35} MRI has not been shown to decrease morbidity or mortality in any group of women. Further, the unique combination of consequences from increased false positive findings and the challenge of accurately conveying patient risk for breast cancer among women at high-risk for breast cancer for whom the test might be appropriate increases the likelihood of errors in therapeutic decision making.

An important limitation of the test is the general lack of capacity to perform MRI-guided biopsy to verify occult findings. This limitation is particularly noteworthy given the high false positive rates associated with the test. When abnormal and suspicious findings are identified, there is no way to confirm that the finding is benign without surgical resection or short interval re-evaluation. Further, protocols for performing breast MRI are not standardized and there are few expert readers for breast MRI. Like mammography, a BI-RADS® lexicon system has been established to guide the interpretation of MRI findings. But unlike mammography, the BI-RADS® lexicon for MRI is less well developed or tested. There are no accreditation programs for breast MRI interpreters and understanding of MRI BI-RADS® reports are generally low in clinical practice. The reproducibility of MRI is not known, but given these factors is likely lower than mammography. Some centers have begun providing breast MRI without a dedicated breast coil.

MRI as a screening test among at women high risk for breast cancer would be an adjunct to, not a substitute for, a screening mammogram. MRI would not be necessary following an abnormal mammogram. MRI is an expensive procedure, more than 10 times the cost of film mammography. CMS only reimburses for MRI as a diagnostic procedure in women at high risk for breast cancer.

Public Health Factors – While MRI is generally available in most major clinical centers, breast MRI requires a breast coil for accuracy, and breast MRI using a breast coil is not widely available. Financial and marketplace incentives exist for increased use of MRI. MRI centers are profit sources for hospitals and are marketed to women as cutting edge technology with distinct advantages over mammography.

Patient acceptability of breast MRI is questionable. MRI is an invasive examination, requiring injection with a contrast agent. Further, patients must lie in an imaging cylinder for 30 to 60

minutes. Many find the conditions claustrophobic and are bothered by the noises associated with the procedure, in some cases requiring sedation and increasing the complexity of the procedure. While women at higher-risk for breast cancer may be more motivated to comply with screening recommendations than average risk women, patient acceptability of breast MRI may be substantially lower than for other imaging modalities such as mammography.

Directing a screening exam to a subpopulation of NBCCEEDP eligible women at higher risk for breast cancer would have considerable impact on program operations. Standard reporting categories and criteria would need to be established for characterizing women as eligible for MRI based on some minimum genetic or breast density criteria. New testing procedures for assessing genetic risk would need to be implemented, confidentiality protected, and associated genetic counseling provided. Data and financial systems would need to be changed to accommodate the collection and reporting of risk criteria. It is likely that case management demands would rise to meet the needs of women receiving non-standard testing and/or to address new patient issues.

Ultrasound

Test Characteristics – Ultrasound is not a primary screening test for women at average risk for breast cancer. Ultrasound has been used as a diagnostic test in women who have suspicious abnormalities based on physical examinations or screening mammography. Studies of screening ultrasound primarily assess the test as an adjunctive screening exam for breast cancer in women for whom mammography is less effective (e.g., women with dense breasts).

Ultrasound is widely used as a diagnostic test to further evaluate masses found on physical examination or mammography. Ultrasound discriminates well between solid lesions that require biopsy and cystic lesions that do not require follow-up. Twenty-five to 50 percent of breast masses are benign cysts. Thus, the role of ultrasound in the evaluation of suspected breast masses is important and well established. A large number of publications have reported that ultrasound can be used effectively to characterize solid breast masses and to estimate the risk of cancer.³⁶

Ultrasound has been studied in several small observational and uncontrolled studies for its ability to detect breast cancer among women who have dense breasts. When used as an adjunctive screening test for women with dense breasts, ultrasound resulted in high false-positive rates leading to large numbers of additional diagnostic procedures with only a small gain in the number of cancers detected.³⁷⁻⁴² However, the American College of Radiology Imaging Network (ACRIN) is conducting a large screening ultrasound trial, which may provide important new information in the near future.

Ultrasound is highly operator dependent. Further, ultrasound is a real time examination and diagnostic value is lost if not interpreted in real time. Despite reduced diagnostic value of static images, failure to capture these images precludes re-review and requires repeating the entire procedure if re-review is needed. A bilateral screening examination can take from 15 to 60 minutes. While most facilities have ultrasound equipment, few providers are trained specifically for whole breast screening examination. Protocols for performing breast ultrasound are not standardized and are not implemented uniformly. Similar to mammography, a BI-RADS®

lexicon system has been established to guide the interpretation of breast ultrasound. But unlike mammography, the BI-RADS® lexicon for ultrasound is less well developed or tested. There is an accreditation program for breast ultrasound but very few sites have applied for accreditation and understanding of ultrasound BI-RADS® reports is generally low in clinical practice. The reproducibility of ultrasound and its interpretation are unclear, but appear lower than mammography.

Because screening with ultrasound may be appropriate only for women with dense breasts and breast ultrasound is used primarily as a diagnostic exam to distinguish between solid lesions that require biopsy and cystic lesions that do not require follow-up, the distinction between a screening and diagnostic ultrasound and associated determination of a woman's routine screening cycle could become confused. CMS reimburses for ultrasound as a diagnostic procedure. The addition of ultrasound as a screening exam to mammography among women with dense breast tissue would double the cost of screening.

Public Health Factors – Ultrasound equipment is available in nearly all facilities that perform breast imaging, but many facilities use ultrasound systems that are old and equipment variability is high. The time requirements of the examination reduce its feasibility as a screening exam. Further, high false positive rates would require increased time for patient education.

Directing a screening exam to a higher risk subpopulation of NBCCEDP eligible women would have considerable impact on program operations. Standard reporting categories and criteria would need to be established for characterizing women as eligible for ultrasound based on some minimum breast density criteria. It is likely that case management demands would rise to meet the needs of women receiving non-standard testing and/or to address new patient issues. The proportion of eligible women that might be classified as having dense breasts and thus eligible for ultrasound screening is unknown, but could be as high as 20 to 25 percent of program eligible women.

Provider education would be required to address issues related to distinctions between screening and diagnostic ultrasound and determinations of women's screening cycles for program eligibility. Education also would be required about program criteria for defining breast density and consequent eligibility for screening ultrasound.

RECOMMENDATIONS

Reimbursement Policies

Following careful review of the test characteristics and public health factors associated with each technology, the NBCCEDP Expert Panel on Breast Cancer Reimbursement Policies discussed potential reimbursement policies and the supporting rationale for each option. Panel members reached consensus on specific recommendations for reimbursement policies and identified the key factors providing the rationale for their recommendation. These recommendations and the key rationale points for each are presented below.

Digital Mammography

Recommendation:

Digital mammography should be reimbursed only at the conventional rate for film mammography. This recommendation should be reassessed following release of DMIST study findings.

Rationale:

- ***Cost*** – The per-test cost of digital mammography would substantially increase screening costs and consequently reduce the total number of women who could be screened by the program.
- ***Access*** – The current limited market penetration of digital mammography suggests that access to the NBCCEDP program will not be substantially affected by the lack of reimbursement for the technology.
- ***Accuracy*** – There is insufficient evidence that digital mammography would contribute to reductions in morbidity/mortality over that achieved by film mammography. This lack of evidence is particularly problematic given the large cost differential between the two technologies.
- ***Reproducibility*** – Lack of standardization and current levels of image and interpretation reproducibility limit the overall accuracy of the exam.

CAD

Recommendation:

CAD should not be reimbursed at this time.

Rationale:

- ***Cost*** – The costs associated with the addition of CAD to current interpretation procedures and the increase in the number of needed follow-up tests for increased false positive findings based on CAD would substantially increase program costs and consequently reduce the total number of women who could be screened by the program. The added cost of 3 CAD procedures would eliminate program funds for one film mammogram
- ***Accuracy*** – There is insufficient evidence that CAD would contribute to reductions in morbidity/mortality over that achieved by film mammography. Further, increased rates of false positive findings would result in unnecessary follow-up procedures and anxiety for women.

MRI

Recommendation:

MRI should not be reimbursed as a screening examination for either (BRCA 1/2) women at high-risk or average risk for breast cancer at this time. This recommendation should be reassessed following release of ACRIN study findings and formal, clear definition of “high risk”.

Rationale:

- ***Program Operations***– Development and implementation of program systems and procedures to direct MRI screening to a subpopulation of women at high risk and to provide necessary case management and genetic counseling support are overly prohibitive for the relatively small potential public health gain.
- ***Accuracy*** – While sensitivity may be increased among women at high risk, false positive rates are unacceptably high, resulting in unnecessary tests and anxiety for women.
- ***Reproducibility*** – Lack of standardization of breast MRI imaging and interpretation limit the overall reproducibility of the exam across settings.
- ***Access*** – Staff time and program resources to implement directed screening could limit resources to provide screening across the population of eligible women.

Ultrasound***Recommendation:***

Ultrasound should not be reimbursed as a screening examination for either normal or high risk women at this time. Reimbursement should continue for ultrasound as a diagnostic procedure for all women after an abnormal breast examination finding and/or mammogram.

Rationale:

- ***Accuracy*** – Test sensitivity is lower than that achieved by mammography and false positive rates among women with dense breasts are higher, resulting in unnecessary test procedures and anxiety for women.
- ***Access*** –Time requirements and the increased costs of the exam, could limit program access to services and disproportionately divert provider time away from other program services.
- ***Reproducibility*** – Lack of standardization of the technology, appropriate credentialing and expertise for operators, as well as equipment variability limits the reproducibility of the exam.
- ***Population characteristics*** – Because younger women are more likely to have denser breast tissue and the risk of breast cancer is substantially lower in these younger age groups, the proportional number of cancers identified from use of the exam directed to this subpopulation would be extremely low.

Research and Surveillance

In addition to specific reimbursement policy recommendations, the panel developed recommendations to address the general paucity of data to inform policy determinations. These recommendations include:

- Fund pilot studies in a subset of NBCCEDP programs to assess current levels of use of CAD.
- Consider pilot assessments of specific reimbursement policy changes on technology practice patterns and the effects of such changes on program operations.

- Initiate planning efforts to more clearly and practically define criteria for high risk.

Future Reimbursement Policy Reviews

The panel recommended that the CDC assess on an annual basis whether new technologies and/or data have emerged that could change existing reimbursement policies. In the presence of new technologies and/or data, an expert panel review of policies should be undertaken. A full policy review should be undertaken at least every 5 years. USPSTF evidence reviews should be utilized to prevent duplication of effort.

BIBLIOGRAPHY

1. U.S. Preventive Services Task Force. Screening for Breast Cancer: Recommendations and Rationale. *Ann Intern Med.* 2002;137((5 Part 1)):344-346.
2. American Cancer Society. *Cancer Facts & Figures*. Atlanta, GA: American Cancer Society; 2005.
3. Ernster VL, Ballard-Barbash R, Barlow WE, et al. Detection of ductal carcinoma in situ in women undergoing screening mammography. *J Natl Cancer Inst.* 2002;94(20):1546-1554.
4. Carney P, Miglioretti D, Yankaskas B, et al. Individual and combined effects of age, breast density, and hormone replacement therapy use on the accuracy of screening mammography. *Ann Intern Med.* 2003;138(3):168-175.
5. Smith-Bindman R, Chu P, Miglioretti D, et al. Physician Predictors of Mammographic Accuracy. *J Natl Cancer Inst.* 2005;97:358-367.
6. Ryerson A, Benard V, Major A. 1991-2002 National Report: Summarizing the first 12 years of partnerships and progress against breast and cervical cancer. *Centers for Disease Control and Prevention*. Available at: <http://www.cdc.gov/cancer/nbccedp/Reports/NationalReport/index.htm>. Accessed April 6, 2005, 2005.
7. Bobo J, Shapiro D, Schulman J, et al. On-schedule mammography rescreening in the National Breast and Cervical Cancer Early Detection Program. *Cancer Epidemiol Biomarkers Prev.* 2004;13(4):620-630.
8. Food and Drug Administration. *21CFR 814.2*: Food and Drug Administration; 2004.
9. Federal Register Notice 03-24361. *Medicare Program: Revised Process for Making Medicare National Coverage Determinations*: Department of Health and Human Services, Centers for Medicare and Medicaid Services; 2003.
10. Center for Medicare and Medicaid Services. Medicare Physician Fee Schedule. *Center for Medicare and Medicaid Services*. Available at: <http://www.cms.hhs.gov/physicians/mpfsapp/step1.asp>. Accessed March 17, 2005.
11. Joy J, Penhoet E, Petitti D, et al., eds. *Saving Women's Lives: Strategies for improving breast cancer detection and diagnosis*. Washington, DC: Institute of Medicine and National Research Council; 2005.
12. Fletcher SW, Elmore JG. Mammographic screening for breast cancer. *N Engl J Med.* 2003;348:1672-1680.
13. Smart C, Byrne C, Smith R, et al. Twenty-year follow-up of the breast cancer diagnosed during the Breast Cancer Detection Demonstration Project. *CA Cancer J Clin.* 1997;47:134-149.
14. Tabar L, Vitak B, Tong H, et al. Beyond randomized controlled trials: organized mammographic screening substantially reduces breast carcinoma mortality. *Cancer.* 2001;91:1724-1731.
15. Nystrom L, Andersson I, Bjurstam N, et al. Long-term effects of mammography screening: updated overview of the Swedish randomized trials. *Lancet.* 2002;359(9310):909-919.
16. Kerlikowski K, Grady D, Barclay J, et al. Effect of age, breast density and family history on the sensitivity of first screening mammography. *JAMA.* 1996;276:33-35.

17. Tabar L, Vitak B, Chen H. The Swedish Two-County Trial twenty years later. Updated mortality results and new insights from long-term follow-up. *Radiol Clin North Am.* 2000;38:625-651.
18. Carlson K, Helvil M, Roubedoux M, et al. Relationship between mammographic screening intervals and size and histology of ductal carcinoma in situ. *AJR Am J Roentgenol.* 1999;172:313-317.
19. Kerlikowski K, Carney P, Geller B, et al. Performance of screening mammography among women with and without a first-degree relative with breast cancer. *Ann Intern Med.* 2000;133:855-863.
20. Elmore JG, Armstrong K, Lehman CD, et al. Screening for Breast Cancer. *JAMA.* 2005;293(10):1245-1256.
21. United States General Accounting Office. *Mammography Capacity Generally Exists to Deliver Services.* Washington, D.C.: US General Accounting Office; April 2002. GAO-02-532.
22. Colbert JA, Kaine EM, Bigby J, et al. The age at which women begin mammographic screening. *Cancer.* 2004;101:1850-1859.
23. National Center for Chronic Disease Prevention and Helath Promotion. Risk Factors and Use of Preventive Services: United States. *Centers for Disease Control and Prevention.* Available at: <http://www.cdc.gov/nccdphp/burdenbook2004/Section03/mammog.htm>. Accessed April, 26, 2005.
24. Lewin JM, D'Orsi CJ, Hendrick RE, et al. Clinical comparison of full-field digital mammography and screen-film mammography for detection of breast cancer. *Am J Roentgenol.* 2002;179:671-677.
25. Lewin JM, Hendrick RE, D'Orsi CJ, et al. Comparison of full-field digital mammography with screen-film mammography for cancer detection: Results of 4,945 paired examinations. *Radiology.* 2001;218(3):873-880.
26. Skaane P, Young K, Skjennald A. Population-based mammography screening: Comparison of screening film and full-field digital mammography with soft-copy reading - The Oslo I Study. *Radiology.* 2003;229:877-880.
27. Skaane P, Skhennald A. Screen-film mammography versus full-field digital mammography with soft copy reading: Randomized trial in a population-based screening program - The Oslo II Study. *Radiology.* 2004;232:197-204.
28. Food and Drug Administration. *Office of Health and Industry Programs Fiscal Year 2003 Annual Report: Radiologic Health Programs.* Washington DC: Food and Drug Administration; 2003.
29. Freer TW, Uliddey MJ. Screening mammography with computer-aided detection: prospective study of 12,860 patients in a community breast center. *Radiology.* 2001;220(3):781-786.
30. Gur D, Sumkin JH, Rockette HE, et al. Changes in breast cancer detection and mammography recall rates after the introduction of a computer-aided detection system. *J Natl Cancer Inst.* 2004;96(3):185-190.
31. Helvil MA, Hodjurski L, Makariou Eea. Sensitivity of non-commercial computer-aided detection system for mammographic breast cancer detection: pilot clinical trial. *Radiology.* 2004;231:208-214.

32. Krupinski EA. An eye-movement study on the use of a CAD information during mammographic search. Paper presented at: Seventh For West Imaging Perception Conference; October 16-18, 1997; Tucson, Az.
33. Krupinski EA. Computer-aided detection in clinical environment. Benefits and challenges for radiologists. *Radiology*. 2004;231:7-9.
34. Warner E, Plewes DB, Hill KA, et al. Surveillance of BRCA1 and BRCA2 mutation carriers with magnetic resonance imaging, ultrasound, mammography, and clinical breast examination. *JAMA*. 2004;292(11):1317-1325.
35. Kriege M, Brekelmans C, Boetes C, et al. Efficacy of MRI and mammography for breast cancer screening in women with a familial or genetic predisposition. *N Engl J Med*. 2004;351:427-437.
36. Stavros AT, Thickman D, Rapp CL, et al. Solid breast nodules: use of sonography to distinguish between benign and malignant lesions. *Radiology*. 1995;196(1):123-134.
37. Irwig L, Houssami N, van Vliet C. New technologies in screening for breast cancer: a systematic review of their accuracy. *Br J Cancer*. 2004;90 (11):2118-2122.
38. Leconte I, Feger C, Galant C, et al. Mammography and subsequent whole-breast sonography of nonpalpable breast cancers: the importance of radiologic breast density. *Am J Roentgenol*. 2003;180(6):1675-1679.
39. Gordon PB, Goldenberg SL. Malignant breast masses detected only by ultrasound. A retrospective review. *Cancer*. 1995;76(4):626-630.
40. Kolb TM, Lichy J, Newhouse JH. Occult cancer in women with dense breasts: detection with screening US -- diagnostic yield and tumor characteristics. *Radiology*. 1998;207(1):191-199.
41. Buchberger W, Niehoff A, Obrist P, et al. Clinically and mammographically occult breast lesions: detection and classification with high-resolution soography. *Semin Ultrasound CT MR*. 2000;21(4):325-336.
42. Buchberger W, DeKoekoek-Doll P, Springer P, et al. Incidental findins on sonography of the breast: clinical significance and diagnostic workup. *AJR Am J Roentgenol*. 1999;173(4):921-927.

APPENDIX A: KEY INFORMANT INTERVIEWS

EVALUATION OF NBCCEDP REIMBURSEMENT POLICIES FOR NEW BREAST AND CERVICAL CANCER SCREENING TECHNOLOGIES

INTRODUCTION

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP), administered by the Centers for Disease Control and Prevention (CDC), helps low income, uninsured, and underserved women gain access to lifesaving screening programs for the early detection of breast and cervical cancers. The program implements a wide range of activities, including a) public education and outreach to increase access to services; b) administration of breast and cervical cancer screening exams and diagnostic testing; c) case management to facilitate access to care and utilization of best practices; and d) professional education and quality assurance to ensure the highest standard of care for women in the program. The NBCCEDP is implemented in all 50 states, 4 U.S. territories, the District of Columbia, and 13 American Indian/Alaska Native organizations. While the program has screened 1.9 million women and provided 4.6 million screening examinations since its inception in 1991, it reaches fewer than 20 percent of eligible women, primarily due to financial limitations.

While the size and complexity of the NBCCEDP poses many challenges, one challenge has been the determination of which screening and diagnostic tests should be paid for by the program. Since the program's inception, scientific advances have resulted not only in improvements to existing screening and diagnostic tests and implementation procedures, but also in the introduction of new technologies. Determinations about whether the NBCCEDP should pay for use of newer screening and diagnostic tests and procedures are complicated. The program must balance a wide range of factors, including for example, standard of care for women in the program, the public health mandate to serve as many women as possible, limited program funds, varying local health services infrastructures, and the impact of changes in program policies on program operating procedures and partners.

The CDC is reviewing the NBCCEDP reimbursement policies for breast and cervical cancer screening and diagnostic services. For breast cancer, the NBCCEDP currently provides reimbursement for film mammography only. Digital mammography, magnetic resonance imaging (MRI), and ultrasound are not reimbursed as screening tests. Computer aided detection (CAD) of digital mammograms is not reimbursed. For cervical cancer, the NBCCEDP provides reimbursement for conventional pap tests, but not for liquid-based pap tests. HPV/DNA testing is reimbursed only for women with ASC-US findings on pap.

Recognizing the complexity of this task and the significant impact on individual BCCEDP programs, the CDC sought to gather additional information about programs' experiences with reimbursement policies. Key informant interviews with NBCCEDP program directors representing eight state programs and two CDC program staff were conducted to gather information about the range of issues that should be considered in CDC's evaluation of its reimbursement policies. Specifically, interviews sought to provide information about:

- a) The type and magnitude of NBCCEDP challenges resulting from current reimbursement policies for screening technologies;

- b) NBCCEDP approaches for addressing challenges associated with current reimbursement policies;
- c) The range and nature of NBCCEDP modifications that would need to be made to adjust to potential modifications of current reimbursement policies for new screening technologies; and
- d) How appropriate balance might be achieved across scientific, infrastructure, programmatic, and public health impact factors in decision-making concerning NBCCEDP reimbursement policies.

METHODS

Interviews were conducted in December, 2004 with NBCCEDP program directors representing eight state programs and two CDC program staff. NBCCEDP program directors volunteered to participate in key informant interviews following an invitation from the NBCCEDP Science and Epidemiology Subcommittee. Program Directors could include other program staff in interviews at their discretion.

Email interview confirmations included an overview of the key informant assessment and a list of questions to be addressed in each interview. Four of the eight interviews with NBCCEDP program directors focused on breast cancer and the remaining four focused on cervical cancer. Interviewees were not restricted, however, from identifying issues beyond the specific cancer focus for their interview and most interviewees addressed reimbursement issues related to both cancers. Each interview was conducted by telephone by Dr. Marianne H. Alciati. Interviews lasted between 45 and 75 minutes. Handwritten interview notes were taken during each interview and a typed summary was prepared following each interview. These summaries were used as the primary information source for analysis. Interviews were tape recorded for verification purposes only and all tapes were destroyed at the end of the analysis.

Each interview summary was reviewed to identify themes and representative issues. Because the purpose of this assessment was to identify the range and nature of reimbursement challenges faced by the NBCCEDP and the sample size was so small, the specific numbers of mentions for each issue and the number of interviewees mentioning each issue was not calculated. However, general comments are presented reflecting whether a particular issue was identified by multiple sites.

LIMITATIONS

It is important to recognize that while the data from these interviews provides a valid picture of issues across the eight programs and from the perspectives of two CDC staff, it does not provide information about the pervasiveness of these issues across NBCCEDP sites and only generally provides perspective on the magnitude of each issue within NBCCEDP programs. While it is generally accurate that the eight programs combined with CDC staff perspectives are typical of NBCCEDP programs, the diversity across NBCCEDP programs and the method for selecting key informant interviewees suggests that the experiences of these programs may not be representative of all programs. It is possible and even likely, that some additional issues or examples exist within other programs. However, these interviews do provide a clear and accurate picture of the majority of issues resulting from current reimbursement policies and changes in policy.

RESULTS

NBCCEDP programs are complex local partnerships, involving extensive networks of providers and health care organizations who deliver screening and diagnostic examinations and help provide and coordinate follow-up care. Reimbursement for screening and diagnostic services is at the heart of the program, representing a significant driving force for how the NBCCEDP programs operate within local communities. Reimbursement policies influence not only what services these programs provide, but also how efficiently they provide those services and how the programs are perceived within their local communities and nationally.

Interviewees identified a broad range of issues associated with existing reimbursement policies as well as historic and current procedures for modifying these policies and communicating revisions. The vast majority of these issues were similar for both breast and cervical cancer reimbursement policies. For this reason, this presentation of results focuses on these issues and their common characteristics with illustrative examples from breast and cervical cancer. While most of the interview results focus on factors that influence demand for new technologies and the challenges posed by current reimbursement policies and review procedures, two significant overriding perspectives were emphasized by the majority of interviewees. First, the NBCCEDP provides a critical public health service and program participants are extremely committed to the NBCCEDP's success. Second, interviewees were extremely appreciative of the opportunity to provide input to the policy review process and of the CDC's commitment to and efforts on behalf of the NBCCEDP.

All NBCCEDP programs are required to reimburse at rates that do not exceed state Medicare rates. Although different state formulas may be used to establish these rates (e.g., urban vs. rural rates), they are quite low and in some cases below the actual cost of delivering the service. Several interviewees pointed out that some costs associated with providing diagnostic and follow-up procedures to this population are not reimbursable using CDC funds. These costs are often paid by state funds (not available in all states), grants, donations, or other sources; or absorbed by the facility or provider. But both of these options add pressure to the system of delivering NBCCEDP services. Newer technologies further exacerbate this pressure because they are often more expensive, although costs tend to decline over time. The consequence of higher costs for individual screening and diagnostic exams is a reduction in the programs' overall capacity to "achieve the greatest good for the greatest number." The reality that the program currently reaches only 20 percent of the eligible target population makes these trade-offs particularly difficult.

Program Consequences: But as revealed in these interviews, the issues go well beyond simple cost calculations. A broad range of consequences result from NBCCEDP reimbursement policies. These are presented below in five broad categories, including a) program performance, b) relationship with providers, c) practice patterns, d) standards of care, and e) program credibility.

Program Performance: Interviewees emphasized that the cost to individual programs of different reimbursement policy decisions have affects well beyond just the cost of individual examinations. In some areas, the failure to reimburse newer technologies has reduced the

number of providers who deliver services for the program causing program shortages. In other cases, providers have used their size or banded together with other providers to pressure the program to reimburse for newer technologies at the approved Medicare rates.

Reduced provider capacity can limit both the programs' ability to meet demand for early detection services as well as cause delays in providing needed services. Delays, in turn impact Minimal Data Element (MDE) reporting and a program's ability to achieve service delivery targets. Examples were noted in NBCCEDP's failure to reimburse for liquid-based pap (LBP) examinations. The paucity of providers performing conventional pap in some areas required women to travel for services, resulting in screening delays or failures to get screening.

Another impact of reimbursement policies on program performance relates to efficiency. In cases of an abnormal pap, use of conventional pap rather than LBP requires a second office visit and additional call-back efforts. This process was noted both to increase the likelihood that follow-up HPV testing would not be accomplished and to drain limited resources due to the need to find women and to pay for a second office visit. Other inefficiencies emerge as well. The need for alternate funding to cover costs for un-reimbursed services takes time and resources, not only to identify sources of funds, but to establish systems that account for separate sources of funding.

Beyond complications associated with existing policies, changes in reimbursement policies have extraordinary implications for program operations. Providers and their staff need to be made aware of new policies, corresponding CPT codes need to be identified and populated in reimbursement systems, data and reporting systems need to be modified, and contract requirements need to be adjusted. Ideally, program policy manuals also would be updated. Some programs indicated that listings of reimbursed procedures are not included in their program manuals because of the unpredictability of policy changes and, in at least one case, the reversal of a policy within a six month timeframe. Failures to include reimbursement information in policy manuals introduces another set of operational requirements, such as development of a separate listing of reimbursable services and increased communication to clarify reimbursement policies and procedures with providers and their staff.

Relationship with Providers: Many interviewees discussed the pressures on providers and their relationship with the program resulting not only from low reimbursement rates, but from a complex interplay of other factors. Providers historically have borne much of the responsibility for ensuring follow-up and treatment for women diagnosed through the program. For breast cancer in particular, medical liability risks are high. Failure to diagnose breast cancer is the primary cause in the U.S. for malpractice claims and the second-leading reason for subsequent claimant payments. Providers also are challenged to keep pace with complex scientific evidence and medical advances. Media publicity further complicates this challenge as patients request and sometimes demand newer technologies that may not be reimbursable through the program. These factors are compounded when newer technologies become available in the market but are not reimbursed by the program and when the NBCCEDP changes what services can be reimbursed under the program.

Many interviewees commented on the extra financial burden to providers when they must absorb the additional cost difference between BCCEDP approved technologies and newer technologies.

While most interviewees commented on the high level of commitment of providers to the NBCCEDP, this added burden is perceived to strain that commitment. In some areas providers have left the program, but more often interviewees indicated that under current policies, providers remain with the program in hopes of upcoming policy changes.

Other consequences for providers were noted, particularly in the ethical dilemma of delivering what, in some cases providers believe to be less than the best care available. In this way, reimbursement policies are viewed as driving the practice of medicine, changing the role of the provider, and changing the patient/provider relationship. Providers in these situations are “pressured” to offer only covered services. In this role, as one interviewee commented, the program is not a “legitimate partner.” Further, many women will not get services until they are assured that they will not be billed. This tension is compounded when patients learn about new technologies through the media, advocacy organizations, or other sources and question the care they receive through the program. Differential treatment as noted by some interviewees fuels distrust between patients and providers.

Reimbursement policies that do not include newer technologies, particularly when they are available within a provider’s health care setting, also increase liability risks. Failure to provide a test or procedure in situations where a cancer is later identified increases the providers’ vulnerability to litigation, particularly if the decision appears based on cost.

All these factors combine to define the relationship between the programs and providers. All interviewees commented on the importance of building and maintaining strong relationships with the providers in their program. Several noted that reimbursement issues have created tension, most notably reflected in ‘uncomfortable’ dialogues in which program staff find themselves ‘arguing with providers’ about interpretations of scientific evidence, or countering a provider’s direct experience with a technology (e.g., LBP is easier to read). Interviewees noted that they expend a lot of time and effort communicating with their providers about the science and rationale behind current reimbursement policies. Some position these policy communications as the program staff and providers on one side and CDC on the other. Often program staff appears to be ‘stretching’ the commitment of providers until policies change in time.

Practice Patterns: It became clear across interviews that different localities adopt newer technologies at different rates. For example, in some areas labs have gone exclusively to LBPs or CAD. In cases where only the newer technology is available, newer technologies are reimbursed at the rates of approved technologies. But newer technologies are often more expensive and the added cost difference must either be absorbed by providers or reimbursed through alternative funds, placing added strain on providers and alternate sources of funds. Several interviewees noted that procedures for providing and billing for new technologies at the rates of approved technologies preclude analysis of the frequency of this practice within the program.

Incompatibilities with existing local health care practices also can lead to inefficiencies and open the door for error. In some cases, the cost difference has been billed directly to women participating in the program. For example, a few interviewees conveyed stories of the cost difference between film mammography and digital mammography with CAD or between

conventional pap and LBP, estimated at about \$60 in each case, being billed directly to women. In some instances, these cases have gone into collections, placing extraordinary and unnecessary burden on women in the program. If an abnormality is identified, some providers back-bill this cost difference to Medicaid. While direct billing to women is disallowed by the program and the situations identified were ultimately resolved, they require considerable staff time and resource as each case must be addressed individually. These situations also extol a price in terms of women's negative experience with the program.

Another example provided by several interviewees of NBCCEDP reimbursed practices being out of step with local practices was the approval for cervical cancer testing using the Digene system. This process allows two samples to be captured during an initial patient visit, one for conventional pap and a second for HPV testing following an abnormal pap. But in most facilities, this procedure applied only to NBCCEDP clients and facilities did not have the capacity to properly store the second sample for potential follow-up. In many cases facilities were unfamiliar with the system altogether.

Another concern stemming from continued use of approved technologies for NBCCEDP women when facilities and providers have transitioned to newer technologies is perceived decline in proficiency by providers for technologies that they no longer perform with the same frequency. For example, one interviewee noted provider concerns about their proficiency interpreting pap slides due to declining frequency associated with increased use of LBP.

Standards of Care: As noted above, providers raise concerns about providing care through the NBCCEDP that is "less than optimal care." But these concerns appear to extend well beyond providers and in reality are fueled both by media coverage and public promotion of medical advances and pharmaceutical marketing efforts directed to providers that may oversell the science behind new technologies. Interviewees raised concerns about both the reality and perception that women in the NBCCEDP receive a different standard of care than those with the financial means to pay for health care. Several interviewees spoke of an emerging, two-tiered system of health care where the poor receive a lower level of care. This raised both public health and ethical concerns.

Program Credibility: Perceptions of a different standard of care for women in the NBCCEDP was viewed as one of several factors that undermine the credibility and reputation of the program. But several interviewees also noted that inefficiencies resulting from reimbursement policies that differ from common practice, as discussed above, also undermine the program's reputation. Resentment was reflected in one local program where providers 'banned together' to demand reimbursement at Medicare rates for LBP. Bad will is also generated when women are billed for differential costs, as in the cases noted above for LBP and CAD.

Perceptions that the NBCCEDP is 'out of step' with current technology has other ramifications as well. One program conveyed an interesting scenario in which their program was unable to participate in a collaborative research study with academia and the Indian Health Service to assess the impact of digital mammography on access to care for underserved, rural populations. The study was viewed as having great potential for expanding the program's reach, but the program's inability to participate because digital mammograms could not be reimbursed was

viewed as reducing program credibility. In this case and more broadly in the program provider relationship, some interviewees indicated these situations threatened the viability of the program as a credible partner in meeting the needs of underserved women.

Finally, several interviewees commented on discrepancies between the reimbursement policies of the NBCCEDP and policies of other federal programs, such as reimbursement by Medicare and approvals for use of new technologies by the Food and Drug Administration. These inconsistencies are confusing and increase the challenge and importance of program communications. Several interviewees also perceived these discrepancies as reducing NBCCEDP credibility.

Review Procedures: The majority of interviewees commented on the historic and current process for revising reimbursement policies. Most expressed appreciation for the interview process and CDC's efforts to include their perspective in the current review of these policies. Continued involvement of multiple perspectives, and particularly NBCCEDP Program Directors was viewed very favorably. Many positive changes were noted in reimbursement policies over the past several years, in particular approvals for loop electrode excision and cold-knife conization of the cervix as diagnostic procedures and HPV testing as follow-up to ASC-US results on pap. Many also noted the improvements resulting from legislative action in 2001 to allow treatment reimbursement through Medicaid.

But the rare instances where policy changes had been made and reversed stood out. Reversals were perceived as program ineffectiveness and "taking something away." This situation required considerable staff time and resources to revise systems and communicate with program partners, and resulted in large credibility costs. In the context of policy revisions, interviewees again emphasized the large ripple effect of changes, requiring changes in recruitment and outreach, data and coding systems for reimbursement, provider education, and MDE reporting.

Several interviewees also commented specifically on the timing of policy revisions. These reviews are not conducted on a fixed schedule and announcements about revisions are not coordinated with impacted program cycles, such as contract renewal dates.

Systems for communicating policy revisions do not appear to be reaching all programs equally. Several interviewees emphasized the importance of enhancing communication about reimbursement policies as well as the process and rationale for policies, both between CDC and the programs, and between program staff and providers. Standardization of the process was often advocated, however, interviewees varied in their perspectives about how flexible final policies should be. Some saw value in flexibility, allowing the individual programs to adjust to local circumstances such as different practice patterns and rates of adoption of new technologies. Others advocated for "hard and fast rules" that they perceived to alleviate confusion shift the burden of unpopular reimbursement decisions to CDC rather than the local program. Some interviewees highlighted the importance of CDC support and assistance translating reimbursement policies into implementation procedures, such as aligning CPT codes to reimbursable procedures.

Finally, across interviewees a number of criteria for reimbursement policy determinations were identified. These included:

- Impact – ensure that policies extend the reach of the NBCCEDP.
- Scientific credibility – policies must be evidence-based, reflecting support for the most effective technologies.
- Cost-benefit – cost benefit analyses that account for all program costs – exam/procedure costs, implementation costs, and credibility costs – must support the overall benefit of new technologies.
- Current and future practice patterns – analysis of the rate of adoption of new technologies and the consequences of different program procedures must be considered.
- Consistency – policies should seek to minimize inconsistencies across national guidelines and federal programs that can adversely affect implementation.

CONCLUSIONS

The NBCCEDP is clearly a critical and valued public health program seeking to meet a need well beyond its resources. CDC, program staff, providers and many other key program partners demonstrate extraordinary commitment to the goals and implementation of the program. But the program is complex, with a broad array of factors influencing its capacity to maximize the delivery of services. Reimbursement policies for program services are at the apex of this web of influences. The key informant interviews conducted for this assessment identified and organized these influencing factors as a basis for more fully and systematically considering the impact of different reimbursement policies on the NBCCEDP. The primary factors identified include program performance, the program's relationship with providers, practice patterns, standards of care, and program credibility.

These interviews also identified strategies for improving the review and implementation process for reimbursement policy revisions, including a) involving multiple perspective, particularly at the program level, b) establishing a standardized process, and c) coordinating the timing of revisions with program cycles impacted by policy revisions. Clear criteria that consider program impact, scientific evidence, cost/benefit, practice patterns and continuity should be applied. And stronger systems must be established for communicating policy decisions and their rational throughout the many partners of the NBCCEDP.

APPENDIX B: EXPERT PANEL PARTICIPANTS

Samantha Allison¹
SVP, Medical Group
GE Healthcare Financial Services

Helen Barr, MD
Director, Division of Mammography
Quality and Radiation Programs
Center for Devices and Radiological Health
Food and Drug Administration

Vernon R. Daly, MD
President
HEUREKA

Mary L. Dolan, MD, MPH
Division Chief, Women's Primary
Healthcare
University of North Carolina School of
Medicine

Carl D'Orsi, MD
Director of Breast Imaging
Emory University

Joann Elmore, MD, MPH
Associate Professor, Medicine
Adjunct Associate Professor, Epidemiology
Section Head, General Internal Medicine,
Harborview Medical Center
Associate Director, Robert Wood Johnson
Clinical Scholars Program
University of Washington

Janelle Guirguis-Blake, MD
Program Director, US Preventive Services
Task Force
Agency for Healthcare Research and Quality

Bradley Hutton, MPH²
Director, Cancer Services Program
New York State Department of Health

Jeffrey Marks, PhD
Associate Professor of Experimental
Surgery, Department of Surgery
Duke University Medical Center

Robert Smith, Ph.D
Director, Cancer Screening
American Cancer Society

Rebecca Smith-Bindman, MD
Associate Professor, Radiology,
Epidemiology and Biostatistics, Obstetrics
Gynecology and Reproductive Medicine
University of California, San Francisco

Barnarese Wheatley, MPH, MA, EDD¹
Health Care Program Administrator
Alameda County Medical Center

Lawrence D. Wagman, M.D., FACS
Professor and Chair, Division of Surgery
City of Hope National Medical Center

Pamela A. Wilcox, RN MBA
Assistant Executive Director
American College of Radiology

1) Member, Breast and Cervical Cancer Early Detection and Control Advisory Committee

2) Director, State Breast and Cervical Cancer Early Detection Program

Cancer Prevention and Control Branch

Main Branch Number (919) 707-5300

Fax Numbers (919) 870-4812 & (919) 870-4811

Christine Ogden, B.S.N.

Chronic Disease Prevention & Control Manager

(919) 707-5208

Christine.ogden@dhhs.nc.gov

Breast and Cervical Cancer Program

Linda Rascoe, B.S.P.H., M.Ed

Program Director

(919) 707-5310

Linda.rascoe@dhhs.nc.gov

Delmonte Jefferson, B.S.

Public Health Program Consultant II

(919) 707-5328

Delmonte.jefferson@dhhs.nc.gov

Michael J. Bramwell, M.A.

Human Services Planner/Evaluator IV

(919) 707-5315

Michael.bramwell@dhhs.nc.gov

Lakeisha Johnson, M.A.

Public Health Educator

(919) 707-5317

Lakeisha.johnson@dhhs.nc.gov

Pat Cannon Fowler, M.P.A., R.N.

Public Health Nurse Consultant

(919) 707-5325

WC: (919) 218-0183

Pat.cannon@dhhs.nc.gov

Paris Mock, B.S.N., R.N.

Public Health Nurse Consultant

(919) 707-5327

WC: (919) 218-6987

Paris.mock@dhhs.nc.gov

Vicki Deem, M.P.A., R.N.

Public Health Nurse Consultant

(919) 707-5324

WC: (919) 218-4270

Vicki.deem@dhhs.nc.gov

Joseph Scott, M.P.A.

Finance Program Supervisor

(919) 707-5326

Joseph.scott@dhhs.nc.gov

Terence Fitz-Simons, Ph.D

BCCCP Data Manager

(919) 707-5312

Terence.fitz-simons@dhhs.nc.gov

Susan West

Administrative Assistant

(919) 707-5301

Susan.west@dhhs.nc.gov

Tammie Hobby

Administrative Assistant

(919) 707-5302

Tammie.hobby@dhhs.nc.gov

Breast Cancer Links

American Cancer Society

Telephone 1-800-ACS-2345

TTY 1-866-228-4327 for hearing-impaired

Website: <http://www.cancer.org>

Breast Cancer Resource Center

Helpline: 1-800-309-0089

Website: <http://www.bcrc.org>

The North Carolina Institute for Public Health

Breast Cancer Resource Directory Project Director

Telephone: 1-800-514-4860

Questions: bcresources@med.unc.edu

Website: <http://bcresourcedirectory.org/>

Cancer Control PLANET

Website: <http://cancercontrolplanet.cancer.gov/>

Contact: <http://cancercontrolplanet.cancer.gov/contact.html>

CDC National Comprehensive Cancer Control Program

Website: <http://www.cdc.gov/cancer/>

Imaginis: The Breast Cancer Resource

Website: <http://imaginis.com>

National Breast and Cervical Early Detection Program

Website: <http://www.cdc.gov/cancer/nbccedp>

National Cancer Institute

Website: <http://www.cancer.gov/>

US Preventive Services Task Force (USPSTF)

Website: <http://www.ahrq.gov/clinic/uspstfix.htm>

Susan G. Komen Breast Cancer Foundation

Helpline: 1-800-462-9273

Website: <http://www.komen.org/>

UNC Lineberger Comprehensive Cancer Center

Website: <http://cancer.med.unc.edu/>

Phone at 919-966-3036

Questions: Dianne Shaw at dgs@med.unc.edu

US Department of Health and Human Services

Health and Human Services Healthfinder

Website: <http://www.healthfinder.gov/>

Date of Release: Immediate

Contact: Beth Darnley
Chief Program Officer
1-800-532-5274
bethd@patientadvocate.org
or Jean Maza
(972) 701-2105
jmaza@komen.org



*Patient Advocate Foundation's Co-Pay Relief Program (CPR)
Announces Additional Financial Help for Breast Cancer Patients Thanks
to a Generous Donation from the Susan G. Komen Breast Cancer Foundation*

Patient Advocate Foundation (PAF) is pleased to announce new additional funding to provide co-payment assistance for patients with breast cancer. On April 1, 2006 the Susan G. Komen Breast Cancer Foundation, headquartered in Dallas, Texas and with more than 100 Affiliates across the United States and globally, became a partner in the Co-Pay Relief Program (CPR) by providing the funds which will enable the program to serve many additional breast cancer patients each month. "The out of pocket expenses associated with a patient's battle against cancer can be extremely difficult to bear, even for those fully covered by insurance. Patient Advocate Foundation, through our Co-Pay Relief Program, is pleased to have this opportunity to serve an even greater number of breast cancer patients who are currently struggling with their pharmaceutical co-payments," said Beth Darnley, Chief Program Officer, Patient Advocate Foundation.

The PAF Co-Pay Relief Program currently provides financial assistance to eligible patients who are being treated for breast, lung, kidney, colon and/or prostate cancers, sarcoma, lymphoma, macular degeneration, diabetes, autoimmune disorders and secondary issues as a result of chemotherapy treatment.

Funds made available by the Susan G. Komen Breast Cancer Foundation will provide direct financial support for pharmaceutical co-payments incurred by insured patients, including new Medicare Part D beneficiaries diagnosed with breast cancer.

"Timeliness of treatment and care is vitally important to all patients with cancer. Now, with the availability of the PAF Co-Pay Relief Program, eligible patients will worry less about expenses associated with their treatment," said Jenny McClendon, manager of the Komen Foundation's national toll free breast health Help Line.

Patients must financially and medically qualify to access co-payment assistance. Patients and physicians can contact the PAF Co-Pay Assistance Program toll-free at 1-866-512-3861 to initiate a request for assistance. Patients who contact PAF Co-Pay Assistance Program for assistance work directly with a call counselor throughout the application process. The patient completes an application on the phone with a call counselor. The completed application is then sent to the caller/applicant for review and signature. The PAF CPR call counselor works directly with the patient as well as the provider of care to obtain necessary medical, insurance and income certification in an expeditious manner.

The ability to efficiently move patients through the application process to approval affords the patient the ability to fully utilize their healthcare coverage and obtain the therapy benefit in a timely manner for the management of their disease. If applicants are deemed medically and financially eligible for assistance, the funds will be provided directly to the insured patients' medical providers or pharmaceutical suppliers. In special cases, patients may receive the funds directly.

The Susan G. Komen Breast Cancer Foundation was established in 1982 by Nancy Brinker to honor the memory of her sister, Susan G. Komen, who died from breast cancer at the age of 36. Today, the Foundation is an international organization with a network of more than 75,000 volunteers working through local Affiliates and events like the Komen Race for the Cure® to eradicate breast cancer as a life-threatening disease. A global leader in the fight against breast cancer, the Foundation fulfills its mission through support of innovative breast cancer research grants, meritorious awards and educational, scientific and community outreach programs around the world. Through fiscal year 2005, the Komen Foundation, together with its Affiliate Network, corporate partners and generous donors, has invested \$630 million in breast cancer research, education, and screening and treatment programs.

For questions about breast health or breast cancer, visit the Komen Foundation's Web site at www.komen.org or call the Komen Foundation's National Toll-Free Breast Care Helpline at 1.800 I'M AWARE® (1.800.462.9273).

Additional information about the PAF Co-Pay Relief Program can be obtained by calling 866-512-3861 or visiting us on the web at www.copays.org or www.patientadvocate.org.

Bibliography

American Cancer Society. Retrieved on September 9, 2005 from <http://www.cancer.org>.

ACR Breast Imaging Reporting and Data System, Breast Imaging Atlas (2003).
ACR BI-RADS® -Mammography (4th Ed) (pp. 194-197). Reston, VA:
American College of Radiology.

American College of Radiology. Retrieved on August 12, 2005 from
http://www.acr.org/s_acr/index.asp.

Soo MS, Rosen EL, Baker JA, Thuy TV, Blythe AB, Negative predictive value of
sonography with mammography in patients with palpable breast lesions.
American Journal of Roentgenology 2001; 177: 1167-1170.

California Department of Health Services (Summer 2000). *Clinical Breast Examination:
Proficiency and Risk management*. Retrieved in January 2005 from Breast Cancer News
via <http://www.ochealthinfo.com/newsletters/bcnews/2000-summer.htm>.

Center for Disease Control and Prevention. Retrieved on August 12, 2005 from
<http://www.cdc.gov>.

Imaginis. Retrieved in May 2005 from http://www.imaginis.com/breasthealth/fibrocystic_breast.

MedicineNet.com. Retrieved on August 10, 2005 from <http://www.medicinet.com>.

Medline Plus®. *Breast CANCER Deaths Continue to Decline*. Retrieved on October 12, 2005
from <http://www.nlm.nih.gov/medlineplus>.

Michigan Cancer Consortium. Retrieved on October 21, 2005 from
<http://www.michigancancer.org>.

National Cancer Institute. Retrieved on August 12, 2005 from <http://www.cancer.gov>.

National Cancer Institute. Retrieved on December 9, 2004 from
<http://www.cancer.gov/cancertopics/pdq/treatment/breast>.

National Cancer Institute. Dictionary of Cancer Terms. Retrieved on October 20-21, 2005
from <http://www.cancer.gov/dictionary/>.